WASTE CONTROL
SPECIALISTS LLC

VIA HAND DELIVERY

March 5, 2010

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RADIOACTIVE
MATERIALS DIVISION

Ms. Susan Jablonski, P.E., Director
Radioactive Materials Division, MC-233
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, Texas 78711-3087

References: (1) Radioactive Material License No. R04100, Amendment 01
CN600616890, RN101702439

Subject: **Application for Administrative Amendment to Radioactive Material License No. R04100 to Authorize Revision to the Quality Assurance Plan and Quality Assurance Procedures for the Low-Level Radioactive Waste Disposal Facility**

Dear Ms. Jablonski:

Waste Control Specialists LLC (WCS) is submitting one original and three copies of an application for an administrative amendment to Radioactive Material License (RML) No. R04100 requesting authorization of revisions to the low-level radioactive waste disposal facility Quality Assurance (QA) Plan and procedures. The revisions are necessary to:

- Indicate the current organizational structure and associated responsibilities;
- Establish a mechanism ("blue sheeting") to make global changes to procedures where required by organizational changes or changes to procedure titles/numbers;
- Remove the "LL" prefix from the document identification number on the procedures that are applicable to all WCS facilities and work activities;
- Incorporate certain minor QA administrative process improvements (for example, the Supplier Qualification Form, QA-7.1-1, was refined and the requirements of procedure LL-QA-15.1, *Control of Non-Conforming Items*, were incorporated into procedure QA-16.1, *Corrective Action Management*, thus allowing cancellation of procedure LL-QA-15.1); and
- Modify procedure LL-QA-8.1, *Identification & Control of Material, Parts & Components*, to reference only the design specification, and not specific information from the design specification, to prevent the potential for inconsistencies between this procedure and TCEQ-approved design specifications.

Enclosed with this letter is a signed General Application for Radioactive Material License form (Part A). Its Attachment 1 contains the revised QA Plan and procedures and Attachment 2 provides the proposed license condition revisions. No adjacent landowner information is

Corporate
5430 LBJ Freeway, Ste. 1700
Three Lincoln Centre
Dallas, TX 75240
Ph. 972.715.9800
Fx. 972.448.1419

Facility
P.O. Box 1129
Andrews, TX 79714
Ph. 888.789.2783
Fx. 505.394.3427

provided with this administrative amendment application, consistent with the requirements of Title 30 of the Texas Administrative Code (TAC), Section 305.62(i)(3).

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

WCS requests that a copy of all correspondence regarding this matter be directly emailed to my attention (skirk@valhi.net) as soon as possible after issuance. If you have any questions or need additional information, please call me at 432-525-8500.

Sincerely,

J. Scott Kirk, CHP
Vice President, Licensing, Corporate Compliance and Radiation Safety Officer

Enclosure

cc: Richard Hyde, P.E., TCEQ – w/o enclosure
Earl Lott, TCEQ – w/o enclosure
Devane Clarke, TCEQ
Alan Batcheller, TCEQ – w/o enclosure
William Dornsife, WCS
Jim Van Vliet, WCS
Linda Beach, WCS
Jeff Skov, WCS
Mike Woodward, Hance Scarborough
Pam Giblin, Baker-Botts
WCS Regulatory Compliance
WCS Records Management

Texas Commission on Environmental Quality
General Application for Radioactive Material License

PART A APPLICATION

I. APPLICANT INFORMATION

A. Applicant's Legal Name: **Waste Control Specialists LLC**

Customer Number (if applicable): **CN600616890**	License Number (if known): **R04100**	
Mailing Address: **P.O. Box 1129**		
City: **Andrews**	State: **Texas**	Zip Code: **79714**
Telephone No.: **432-525-8500**	Fax No.: **575-394-3427**	Email Address:

B. Radiation Safety Officer: **Scott Kirk, CHP**

Mailing Address: **P.O. Box 1129**		
City: **Andrews**	State: **Texas**	Zip Code: **79714**
Telephone No.: **432-525-8500**	Fax No.: **575-394-3427**	Email Address: **skirk@valhi.net**

C. Official Contact Name (if other than the RSO): **N/A**

Title:		
Mailing Address:		
City:	State:	Zip Code:
Telephone No.:	Fax No.:	Email Address:

II. IMPORTANT GENERAL INFORMATION

A. Is confidential information submitted with this application?	☐ YES ☒ NO
B. Is a TCEQ Core Data Form (TCEQ Form No. 10400) attached? The TCEQ **requires** that a Core Data Form be submitted on all incoming applications unless a Regulated Entity and Customer Reference Number have been issued by the TCEQ and no core data information has changed. For more information regarding the Core Data Form, call (512) 239-5175 or go to the TCEQ Web site at www.tceq.state.tx.us/permitting/central_registry/guidance.html.	☐ YES ☒ NO

Texas Commission on Environmental Quality
General Application for Radioactive Material License

PART A APPLICATION

III. FACILITY AND SOURCE INFORMATION

A. Site Name and Location(s) at which radioactive material will be possessed and/or used:

Waste Control Specialists LLC, Andrews County, Texas

Regulated Entity Number (if applicable): **RN101702439**

Physical Location, Address, or Description: : **9998 State Highway 176 West**

City: **Andrews**	County: **Andrews**	Zip Code: **79714**

B. Principal Company Product or Business: **Commercial Waste Management Facility**

C. Locations where records will be kept: **9998 State Highway 176 West**

Physical Location, Address, or Description:

Approximately one mile north of State Highway 176 at 9044 NW 9999 on State Line Road, 250 feet east of the Texas and New Mexico State Line (30 miles west of Andrews, Texas)

City: **Andrews**	County: **Andrews**	Zip Code: **79714**

D. Radioactive Material Data:

(1) Element and mass number	(2) Chemical or physical form	(3) Maximum activity requested	(4) Use of each form
No change requested	**No change requested**	**No change requested**	**No change requested**

IV. TYPE OF LICENSE ACTION REQUESTED

A. Action Requested: ☐ Initial Issuance ☐ Renewal ☒ Amendment ☐ Termination

B. For a new license, check the type of license requested: **N/A**

☐ Source Material Recovery
☐ Radioactive Waste Processing and Storage (describe in Part B of application)
☐ Low-Level Radioactive Waste Disposal
☐ Disposal of NORM Waste from Public Water Systems
☐ Commercial By-product Material Disposal
☐ Alternative Methods of Disposal

C. For an amendment, indicate the type: ☐ Major Amendment ☐ Minor Amendment ☒ Administrative Amendment

D. Describe amendment request and regulatory justification for amendment: **This amendment request is submitted to obtain TCEQ authorization to make minor changes to the Quality Assurance (QA) Plan and procedures. License Condition No. 98 of Radioactive Material License No. R04100 requires the Licensee to obtain an amendment to the license in order to revise the QA Plan. The minor changes are described in the cover letter for this application. The QA Plan and procedure revisions are in Attachment 1. Proposed draft text for the license is in Attachment 2.**

Texas Commission on Environmental Quality
General Application for Radioactive Material License

PART A APPLICATION

V. LICENSE FEE INFORMATION			
A. Fee paid for this application:			$ **N/A**
B. Has the Radioactive Material License Payment Submittal Form (TCEQ-20462) been submitted to the Cashier's Office?			☐ YES ☐ NO ☒ N/A
VI. PUBLIC NOTICE INFORMATION *(complete for initial issuance, renewal, major and minor amendments)*			
A. Responsible Person: **NOT APPLICABLE – ADMINISTRATIVE AMENDMENT REQUEST**			
Name:		Title:	
Mailing Address:			
City:	State:		Zip Code:
Telephone No.:	Fax No.:	E-mail Address:	
B. Technical Contact:			
Company Name:			
Name:		Title:	
Mailing Address:			
City: Andrews	State:		Zip Code:
Telephone No.:	Fax No.:	E-mail Address:	
C. Name of Public Place application may be viewed:			
Physical Address:			
City:		County:	
The public place has granted authorization to place the application for public viewing and copying? **N/A**			☐ YES ☐ NO
D. Is the list of adjacent landowners included with the application? **N/A**			☐ YES ☐ NO
E. Is map of the adjacent landowners included with the application? **N/A**			☐ YES ☐ NO
F. Have the mailing labels with the adjacent landowners names and mailing addresses been included with the application, as per instructions? **N/A**			☐ YES ☐ NO
VII. DELINQUENT FEES AND PENALTIES			
Notice: This form will not be processed until all delinquent fees and/or penalties owed to the TCEQ or the Office of the Attorney General on behalf of the TCEQ are paid in accordance with the "Delinquent Fee and Penalty Protocol." For more information regarding Delinquent Fees and Penalties, go to the TCEQ Web site at: www.tceq.state.tx.us/agency/delin/index.html.			

Texas Commission on Environmental Quality
General Application for Radioactive Material License

VIII. SIGNATURE

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

NAME: Scott Kirk TITLE: VP Licensing, Corporate Compliance & RSO

SIGNATURE: Scott Kirk DATE: 3-5-2010

Original Signature Required

SUBSCRIBED AND SWORN to before me by the said Scott Kirk

On this 5 day of March, 2010

My commission expires on the 21 day of September, 2010

ELIZABETH RABAEY NOTARY PUBLIC STATE OF TEXAS EXPIRES 09-21-2010

Elizabeth Rabaey
Notary Public in and for

Travis County, Texas

(Note: Application must bear signature and seal of notary public)

PART B APPLICATION

Additional technical information must be submitted as Part B of the application. In addition to the information provided in the Part A application, specific information is required as part of the application under Texas Health & Safety Code Chapter 401 and 30 TAC §§305.45, 305.54, 336.205, 336.207, 336.613, 336.615, 336.704, 336.705, 336.706, 336.707, 336.708, 336.709, 336.710, 336.711, 336.1007, 336.1109, 336.1111, 336.1211, and 336.1213, as applicable.

Application materials must be submitted according to applicable requirements of the Texas Engineering Practice Act, the Texas Geoscience Practice Act, and the Professional Land Surveying Practices Act.

ATTACHMENT 1

WASTE CONTROL SPECIALISTS LLC

LIST OF QUALITY ASSURANCE PROCEDURES

QAP-100 - Quality Assurance Plan

QA-2.1 - Quality Planning

QA-2.2 - QA Program Management Review

QA-2.3 - Trending of Quality Assurance and Quality Control Data

LL-QA-3.2 - Design Controls for Contractors

QA-4.1 - Procurement Document Control

QA-5.1 - Standard Operating Procedures and Work Instructions

QA-6.1 - Document Control

QA-7.1 - Supplier Qualification

LL-QA-8.1 - Identification and Control of Materials, Parts and Components

QA-9.1 - Special Processes Qualification and Controls

QA-10.1 - Inspections

QA-11.1 - Test Control

QA-12.1 - Control of Measuring and Testing Equipment

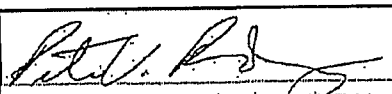
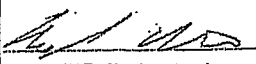
QA-16.1 - Corrective Action

QA-16.2 - Stop Work

QA-17.1 - Quality Assurance Records

QA-18.1 – Audits

QUALITY ASSURANCE PLAN

PLAN APPROVALS:		
Pete Rodriguez		1/25/10
DIRECTOR OF QUALITY ASSURANCE	DIRECTOR OF QUALITY ASSURANCE (signature)	DATE
Rodney Baltzer		1/26/10
PRESIDENT	PRESIDENT (signature)	DATE

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QUALITY ASSURANCE PROGRAM POLICY STATEMENT

Waste Control Specialists LLC (WCS) has developed a comprehensive quality assurance program that establishes the quality assurance requirements and applicable management controls to control quality-affecting items and work activities for WCS waste facilities. The resulting WCS Quality Assurance (QA) Program applies as written to WCS quality affecting activities (i.e., deeds, actions, processes, tasks or work, which influence the achievement or verification of quality requirements and objectives for Quality Level 1 and 2 Structures, Systems, Components (SSC) and related work activities. This program consists of this policy statement, Quality Assurance Plan (QAP) and the WCS implementing procedures.

The WCS QA Plan and its implementing procedures defines the actions to be taken by WCS management and employees during the performance of quality affecting activities to ensure QA requirements are consistently met. This QA program is based on line and staff organizations being responsible and held accountable for the quality of their assigned work. The QA organization is charged with verifying the achievement of quality through audits, surveillances, assessments and reviews.

This program has my complete support and is to be followed at all times. Compliance with the requirements of the WCS QA program is mandatory.

The authority to administer the WCS QA Program described in the WCS QA Plan and implementing procedures is assigned to the WCS Quality Assurance Director.

All WCS Managers and employees are responsible for implementing the procedures required by this program. WCS personnel are given authority commensurate with their responsibility, including the authority to stop work that does not conform to established requirements. Stop-work authority, including investigation, resolution, completion of corrective actions and authorization for restarting work, is to be exercised in accordance with procedures.

All matters concerning quality that cannot be resolved at the normal organizational interfaces shall be referred to me for final resolution.

Rodney A. Baltzer
WCS President

INTRODUCTION

Waste Control Specialists LLC (WCS) maintains full responsibility for ensuring that WCS Waste Disposal Facilities are designed, constructed, operated (including the receipt, handling, and emplacement of waste) and decommissioned in compliance with the applicable regulatory requirements, specified design requirements and applicable industry standards in a manner to protect the health and safety of the employees and the public and to protect the environment.

The WCS QA Program described in this plan covers design, construction, and operations, of the WCS facilities. The design of the facility includes (1) characterization of the geologic setting, (2) predicting the long-term stability of the site, (3) predicting the environmental interactions, (4) planning and specifying processes for handling waste, (5) specifying the requirements for constructing and handling waste.

The WCS QA Plan is written to establish the quality assurance requirements and management controls applicable to quality affecting activities performed by WCS and WCS contractors. Selective application of these controls is managed utilizing a classification and grading process for each WCS business unit.

The following subsections provide the description of the applicable QA requirements and management controls for WCS quality affecting work activities.

SECTION 1
ORGANIZATION

WCS has full responsibility to ensure that the facility is designed, constructed, tested and operated in a manner to protect the health and safety of the public. This responsibility begins with initial design and continues throughout the life of the facility. The WCS QA Program is designed to ensure that the necessary quality requirements for structures, systems, components and work activities are achieved. This objective is attained by ensuring that the organizational framework and the responsibility assignments are such that quality is achieved and maintained by those who have been assigned responsibility for performing work and, quality achievement is verified by individuals or organizations not directly responsible for performing the work.

The WCS Chief Executive Officer is the executive in charge of WCS. The Chief Executive Officer has assigned the WCS President as the executive in charge of managing all WCS functional areas. The WCS President establishes the basic policies of the WCS QA Program. The policies described in this QA Plan are transmitted to all levels of management and are implemented through approved procedures. The WCS QA organization has responsibility for development, management and verifying the proper implementation of the WCS QA Plan.

ORGANIZATIONAL RESPONSIBILITIES AND AUTHORITIES

The WCS President is the highest level of management responsible for WCS' QA policies, goals, and objectives. Reporting to the President are the Sr Vice President Planning and Business Development; Executive Vice President, Licensing; Executive Vice President, Operations; Vice President Community Relations, Director, Quality Assurance and Quality Control, Director, Information Technology and the Chief Financial Officer. For the purposes of this document, only the positions that have QA responsibilities and authority will be described in this document.

The WCS organization chart is included as Chart 1 and can be viewed at the end of this document.

EXECUTIVE VICE PRESIDENT, LICENSING RESPONSIBILITIES AND AUTHORITIES

The Executive Vice President, Licensing is responsible for the development, submittal and compliance of the license application and permits. Positions reporting to the Executive Vice President, Licensing include the Vice President, Licensing.

EXECUTIVE VICE PRESIDENT, OPERATIONS RESPONSIBILITIES AND AUTHORITIES

The Executive Vice President, Operations is responsible for the overall operation and administration of the facility. The Executive Vice President, Operations is responsible for ensuring that the facility complies with all applicable regulatory requirements. In the discharge of these responsibilities, the Executive Vice President, Operations takes direction from the President. Reporting to the Executive Vice President, Operations is the Vice President and General Manager.The Vice President and General Manager directs the activities of the following facility functional groups:

- Operations
- Environmental
- Health, Safety and Security
- VP Licensing, Corporate Compliance & Radiation Safety Officer
- Technical Services
- Facility Construction
- Engineering and Maintenance

CHIEF FINANCIAL OFFICER RESPONSIBILITIES AND AUTHORITIES

The Chief Financial Officer has overall responsibilities for managing the administrative services for WCS. These administrative services include both QA and non QA areas. The QA functional areas managed includes Records Management, Procedure Administration, Document Control and Purchasing. These areas are managed by the Director, Contracts and Administrative Services.

QUALITY ASSURANCE RESPONSIBILITIES AND AUTHORITIES

WCS QA is responsible for establishing a documented Quality Assurance Program and verifying its effective implementation. QA personnel are organizationally independent from engineering, construction, operational, and decommissioning activities. QA personnel have the freedom and responsibility to identify quality problems; initiate, recommend or provide solutions, and to verify and report such solutions directly to management. QA personnel have the authority and responsibility to stop work in accordance with procedures when the continuance of the work could produce results adverse to quality.

The QA organization is responsible for the following activities.

- Oversight of the quality of design, construction, inspection, testing and operations.
- Oversight of supplier QA programs, including development and approval of qualified supplier list, conducting audits and surveillances of supplier QA programs, and the review, approval and control of supplier and procurement QA records.
- Development, maintenance and approval of the WCS QA procedures.
- Review and approve procedures for quality affecting work activities
- Management of the QA Audit and Surveillance Program.
- Specifying QA requirements for quality affecting procurements.
- Administering the non-conformance and corrective action processes including tracking and trending.

During design, construction and operation, QA is considered part of the team and as such is included in day-to-day facility meetings and decisions with the facility staff. QA employees are able to make quality assurance decisions and have sufficient authority, access to work areas, and organizational freedom to:

- Identify quality problems,
- Initiate, recommend solutions to quality problems through designated channels,
- Verify implementation of solutions and ensure that further processing, delivery, installation, or use is controlled until proper disposition of nonconformances, deficiencies or unsatisfactory conditions has occurred,
- Have direct access to highest levels of management, and
- Be sufficiently independent from cost and schedule considerations and have stop-work authority.

DELEGATION OF WORK

The delegation of work between WCS and contractors is identified in procurement documents. In all cases of delegation, WCS retains the overall responsibility for all work performed under the direction of WCS. Responsible WCS managers have the authority to delegate tasks to another qualified individual within their organization provided the designated individual possesses the required qualifications. The responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements.

RESOLUTION OF DISPUTES

Disputes involving differences of opinion on quality matters or issues are brought to the attention of WCS line management, and if not resolved by the individual's manager, are elevated progressively to the QA Director. If satisfactory resolution cannot be obtained at that level, the matter is then elevated to the WCS President for final resolution.

STOP WORK AUTHORITY

Stop work authority at WCS is vested in each WCS employee whenever the health and safety of workers or the public, or the protection of the environment is involved. Employees also have stop work authority when continued work in any area will produce results adverse to quality. A WCS procedure addressing "Stop Work" defines the criteria, authorities and responsibilities for stopping work and the documentation and corrective actions required before resuming work. This process ensures that quality affecting work activities are controlled until the identified condition has been resolved.

SECTION 2
QUALITY ASSURANCE PROGRAM

QA PROGRAM BASIS

The WCS Quality Assurance Plan complies with regulatory requirements applicable to the specific WCS business unit and applies to all levels of the organization, including contractors, who perform quality-affecting work activities.

For purposes of understanding the applicability of the WCS QA Program, "Quality Affecting" is defined as "deeds, actions, processes, tasks or work which influence the achievement or verification of quality requirements and objectives for Quality Level 1and 2 structures, systems and components (SSCs) and their associated work activities."

ASME NQA-1 *Quality Assurance Requirements for Nuclear Facility Applications* is used in conjunction with U.S. Nuclear Regulatory Commission, NUREG-1293, "Quality Assurance Guidance for Low-Level Radioactive Disposal Facility," and other applicable regulatory requirements and provides detailed guidance for the WCS QA Program. This QA Plan states WCS policies, assigns responsibilities and specifies requirements for managing the implementation of QA Program at WCS. The 18 criteria of ASME NQA-1 have been addressed to identify the total set of QA controls required for WCS work activities

The QA Program requires that quality affecting work be planned and accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The QA Program provides for any special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality

WCS QUALITY LEVELS AND APPLICATION OF QA CONTROLS

Three QA Levels have been established and apply to WCS radioactive waste disposal facilities from design to construction, operation, and decommission. The three quality levels are defined as follows.

Quality Level	Description
1	Structures, Systems and Components (SSCs) and related quality affecting work activities relied on to satisfy facility performance objectives.
2	SSCs and related work activities not relied on to satisfy facility performance requirements but whose performance may be important to ensuring operational or WCS mission-critical goals.
3	SSCs that are not Quality Level-1, or Quality Level-2.

The process of classification and grading for Quality Level SSCs and related work activities is prescribed in a WCS procedure.

The following criterion is applicable to the grading for SSCs and related work activities:

- Function and end use;
- Consequence of failure;
- Importance of the data being collected or analyzed;
- Complexity of the design or implementation of the activity;
- Reliability of the associated processes and components;
- Reproducibility of results;

- Uniqueness of the item or service quality;
- Necessity for special controls or processes;
- Degree which functional compliance can be demonstrated through inspection or test;
- Other relevant factor and risk as applicable.

QUALITY ASSURANCE INDOCTRINATION AND TRAINING

WCS employees who perform quality affecting work activities will receive QA Indoctrination Training. This training includes general criteria, including introduction to applicable codes, standards, QA Procedures, QA Program elements and job responsibilities and authorities. WCS personnel assigned to perform quality affecting work activities are also required to complete training in the specific procedures needed to perform their job roles and responsibilities as assigned by their supervisor. Detailed QA training is provided on the QA Program and job specific procedures prior to an employee beginning work. WCS managers are responsible for assuring that personnel performing work under their supervision are appropriately trained.

MANAGEMENT ASSESSMENT

WCS conducts an annual management assessment to determine if the WCS QA Program is effectively implemented. Recommendations resulting from the assessment are provided to WCS management for action.

As part of the WCS verification process, line managers perform assessments of their respective work areas for the purpose of self-identification of conditions adverse to quality and performance improvement. The assessment results are reviewed by WCS management for the purpose of validating the adequacy of implementation of the QA Program and to direct any needed changes for program or process improvements.

QUALITY ASSURANCE PROGRAM STATUS REPORTING

WCS QA regularly advises WCS management regarding the status of the QA program. The status normally includes the results of reviews conducted on audit reports, internal surveillance reports, corrective action reports, management assessments, etc. Corrective action is initiated as necessary based on the review discussion.

SECTION 3
DESIGN CONTROL

WCS is responsible for the management and implementation the design control program. WCS managers are also responsible for ensuring that contractors performing design activities affecting quality implement an effective design control program. WCS QA is responsible for reviewing and approving contractor QA Plans.

The scope of the design program shall include, as needed to develop a compliant design, field design engineering, physics, seismic, stress, thermal, and geotechnical; associated computer programs; compatibility of materials; accessibility for in-service inspection, maintenance, and repair; quality standards.

DESIGN INPUT CONTROL

Applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes and standards) shall be controlled to the following requirements:

- Design inputs shall be identified/documented and their selection reviewed/approved.
- Design inputs shall be specified and approved in a timely manner. Design inputs shall provide the necessary details to permit design to be carried out in a manner that provides a consistent basis for making design decisions, accomplishing design verification and evaluating design changes.
- Changes from approved design inputs and reasons for the changes shall be identified, approved, documented and controlled.
- Design inputs based on assumptions that require re-verification shall be identified and controlled by the appropriate procedures.

DESIGN PROCESS

The design process shall be controlled as follows:

- Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out in a compliant and efficient manner.
- Design documents shall be adequate to support design, fabrication, construction, test, inspection, and operation.
- Appropriate standards shall be identified and documented.
- Changes from specified standards, including the reasons for the change, shall be identified, approved, documented and controlled.
- Procedural controls shall be established for selecting and reviewing design methods, materials, parts, equipment and processes that are essential to the function of an item and suitability of application.
- Applicable information derived from experience reports, or other documentation, shall be made available as design input.
- Design documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references and units such that a person technically qualified in the subject discipline can understand the documents and verify their adequacy without recourse to the originator of the design document.
- Design drawings, specifications or other design documents shall contain appropriate inspection, examination and testing acceptance criteria.

DESIGN ANALYSIS

Design analyses shall be planned, controlled and documented. Design analysis documents shall be legible, in a form suitable for reproduction, filing and retrieval. Design calculations shall be identifiable by subject, originator, reviewer and date or by other designators in order that approved calculations are traceable.

- Computer software used to calculate or develop data that is used as a design input shall be verified, validated and documented.
- Design analyses documentation shall include:
- Definition of the objective of the analyses,
- Definition of design inputs and their sources,
- Results of literature searches or other applicable background data,
- Identification of assumptions and designation of those that must be verified as the design proceeds,
- Identification of any computer calculation, including computer type, computer program, revision level, inputs, outputs and the bases (or reference thereto),
- Identification of analysis methods utilized,
- Identification of the design/analysis results and demonstration that applicable acceptance criteria is met,
- The conclusion of the design/analysis, and
- Design/analysis final review and approval.

DESIGN VERIFICATION

The following design control requirements shall be applied to verify the adequacy of design:

- Design verification is required for quality affecting design documents, and shall be performed using one or a combination of the design review, alternate calculations and/or qualification testing methods.
- The particular design verification method used shall be documented.
- Results of design verification shall be documented.
- Competent individuals or groups, other than those, who performed the original design (but may be from the same engineering organization), shall perform design verification. If necessary, this verification may be performed by the originator's supervisor provided that the engineering supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the engineering discipline competent to perform the verification.

Design verification shall be performed at appropriate times during the design process.

Verification shall be performed before release for procurement, manufacture or construction, or release to another organization for use in other design work. In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to other engineering organizations or disciplines to support schedule requirements. Unverified portions of the design shall be clearly identified and procedurally controlled. In all cases, design verification shall be completed before relying on the item to perform its function. Extent of design verification required shall be a function of the importance to safety, complexity of design, degree of standardization, state of the art and similarity with previously proven designs.

Design reviews shall be controlled and performed to ensure:

- Design inputs were correctly selected and incorporated.
- Assumptions necessary to perform the design work were adequately described, reasonable and, where necessary, re-verified.
- An appropriate design method was used.
- The design output is reasonable compared to the applicable design inputs.
- The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing documents.

The appropriateness of assumptions, input data, and the computer program or other calculation methods used, shall be evaluated and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses.

If design adequacy is to be verified by qualification testing, the tests shall be identified, controlled and documented according to the following:

- The test configuration shall be defined and documented.
- Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse design conditions.
- If the tests verify only specific design features, then the other features of the design shall be verified by other means.
- Test results shall be documented and evaluated to ensure that test requirements have been met.
- If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and re-tested or otherwise verified to ensure satisfactory performance.

DESIGN CHANGE CONTROL

Design changes shall be controlled according to the following requirements:

- Changes to final designs and nonconforming items dispositioned as "use-as-is" or "repair," shall have documented justification for use and are subject to the same design control measures and reviews as those applied to the original design.
- Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.
- Changes shall be approved by the same engineering disciplines/groups that reviewed and approved the original design documents, with the following clarifications:
    - If the engineering discipline/group that originally was responsible for approving a particular design document is no longer responsible, then a new organization shall be designated.
    - The designated engineering disciplines/groups shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

- The design process and design verification methods and implementing documents shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These design deficiencies shall be documented.
- When a field change is approved other than revision to the affected design documents, field changes shall be incorporated into affected design documents when such incorporation is appropriate.

DESIGN INTERFACE CONTROL

Design interfaces shall be identified and controlled. Design efforts shall be coordinated among interfacing organizations. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among interfacing design organizations for the review, approval, release, distribution and revision of documents involving design interfaces. Project design information transmitted across interfaces shall be documented and controlled. Transmittals of design information and/or documents shall reflect the status of the transmitted information and documents.

SECTION 4
PROCUREMENT DOCUMENT CONTROL

WCS is responsible for developing and submitting procurement documents. WCS managers are responsible for ensuring that procurement documents are complete and in accordance with the QA program procedures.

WCS quality affecting procurements shall be issued to suppliers that have been evaluated and qualified as acceptable for the specified scope of work, equipment and services to be provided. The material, equipment and/or services shall be procured from approved suppliers utilizing procurement documents approved by WCS. To the extent necessary, procurement documents require suppliers to have a quality assurance program consistent with the applicable WCS and regulatory requirements.

PROCUREMENT DOCUMENT CONTENT

WCS procurement documents issued for quality affecting items or services shall include the following items, as applicable to the procured material, equipment or service:

- Statement of the scope of work to be performed by the supplier.
- Technical requirements including:
  - Design bases, identified or referenced in the procurement documents.
  - Specific documents (i.e., drawings, codes, standards, regulations, procedures or specification) describing the technical requirements of the material, equipment or services to be furnished shall be specified.
  - Tests, inspections or acceptance criteria that WCS will use to monitor and evaluate the performance of the supplier shall be specified.
- Quality Assurance requirements including:
  - A requirement for the supplier to have a documented quality assurance program that implements applicable WCS and regulatory requirements. The extent of the quality assurance program shall depend on the scope, nature or complexity of the material, equipment or service to be procured. The supplier shall also incorporate the appropriate requirements into any sub tier supplier issued procurement documents.
- Right of access to supplier, including sub tier, facilities and records for inspection or audit by WCS, or other designee authorized by WCS.
- Provisions for establishing witness/inspection hold points beyond which work cannot proceed by the supplier without WCS authorization.
- Documentation required to be submitted to WCS for information, review or acceptance shall be identified along with a document submittal schedule. Record retention times, disposition requirements and record maintenance responsibilities shall be identified for documentation that will become quality assurance records.
- Requirements for the supplier to report to WCS in writing adverse quality conditions resulting in work stoppages and nonconformances. WCS approval of partial and full work releases and disposition of nonconformances is required.

PROCUREMENT DOCUMENT REVIEW AND APPROVAL

Procurement document reviews shall be performed and documented before issuing the procurement documents to the supplier. A review of the procurement documents and any changes thereto shall be made to verify that documents include all pertinent technical and quality assurance program requirements and contain appropriate provisions to ensure that material, equipment or services will meet the requirements.

Personnel who have access to pertinent information and have an adequate understanding of the requirements and scope of the procurement shall perform reviews of the procurement documents. Reviewers shall include representatives from the technical and QA organizations.

PROCUREMENT DOCUMENT CHANGE

Procurement document changes affecting the technical or quality assurance requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

SECTION 5
INSTRUCTIONS, PROCEDURES AND DRAWING

Quality affecting work activities will be conducted in accordance with instructions, procedures and or drawings as appropriate to the activity being performed.

Instructions, procedures and drawings shall include appropriate quantitative and qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

WCS QA is responsible for the development of the QA Procedures related to QA responsibilities. WCS managers are responsible for developing quality affecting documents or procedures that control the administrative and technical work processes.

WCS employees and contractors performing quality affecting work shall comply with instructions, procedures and drawings; however, when work cannot be accomplished as described in the procedure, instruction or drawing or accomplishment of such work would result in an undesirable situation, a condition adverse to quality, or an unacceptable safety risk, the work shall be suspended until a solution can be determined.

TYPES OF DOCUMENTS

The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Documents include procedures, instructions, drawings and specifications. Work controlling procedures may also utilize approved checklists, travelers or other means to assure process requirements are met including prerequisite requirements prior to starting work. Procedures provide a consistent method for process performance and documentation of completion as well as ensure specified safety and environmental conditions are maintained.

CONTENT OF DOCUMENTS

Documents shall include or reference the following information as appropriate to the work to be performed:

- Responsibilities of the organizations affected by the document,
- Quality, technical and regulatory requirements,
- A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests and other operations, if applicable,
- Quantitative or qualitative acceptance criteria sufficient for determining that prescribed activities have been satisfactorily accomplished,
- Prerequisites, limits, precautions, process parameters and environmental conditions,
- In-process quality verification points and hold points,
- Methods for demonstrating that the work was performed as required,
- Identification of QA records generated by the document.

Scientific investigations will be performed utilizing WCS procedures and/or nationally recognized standards. Standards used without modification require documentation by reference only. If a deviation from the standard or establishment of specifically prepared procedures is deemed appropriate, the modifications or new methods should be documented in sufficient detail to be repeatable and should be evaluated, justified and approved.

SECTION 6
DOCUMENT CONTROL

WCS employees and contractors are responsible for developing, maintaining and using controlled documents. WCS Document Control is responsible for distributing controlled documents and ensuring that these documents are available for use.

TYPES OF DOCUMENTS

Instructions, procedures, drawings and other documents specifying quality requirements or prescribing quality affecting activities shall be controlled in accordance with this section. WCS documents controlled under the WCS QA Program include, procedures, design requirements document, design basis documents, engineering specifications, instructions, drawings, calculations, procurement documents, computer codes, technical reports and documents that need to be controlled due to being input to other WCS design documents or used for construction and operations affecting quality.

PREPARING AND REVIEWING DOCUMENTS

The document control system shall ensure that the identification of documents to be controlled and their specified distribution are proceduralized. The system shall further ensure that the responsibility for preparing, reviewing, approving and issuing documents shall be assigned by procedure to the appropriate WCS manager. Documents specifying quality requirements or prescribing quality affecting activities shall be reviewed in accordance with applicable procedures for adequacy, correctness and completeness and by the QA organization as specified by procedure, prior to approval and issuance.

CONTROLLING THE DISTRIBUTION AND USE OF DOCUMENTS

Controlled documents are available on the WCS network and appropriate controls are to be implemented to ensure that the most current documents are posted. If needed, documents needing to be placed under document control can be transmitted to Document Control with the distribution list for document holders. Document Control shall enter the document into the Document Control master list of controlled documents, assign document control numbers, complete transmittal forms and distribute the documents and transmittal form to the document holders. Document holders shall acknowledge receipt on the transmittal and send the acknowledgement to the Document Control. The up-to-date master listing of controlled documents will be made continuously available to document holders to verify that they have the current revisions.

Controlled documents can also be made available on line to WCS employees provided appropriate controls are implemented to control the documents.

The distribution and use of documents, including changes and editorial corrections to documents, shall be controlled as described below:

- Documents used to perform work shall be distributed to, and used at, the work location.
- Effective dates shall be established for approved documents. If an effective date is not documented on the coversheet then the document is assumed to be effective on the date approved.
- The disposition of obsolete or superseded documents shall be controlled. Controlling instructions are contained in the applicable procedures for document control and records management.
- The WCS document control master list shall be used to identify the current status of each document that is required to be controlled.

CHANGES TO DOCUMENTS

Changes to documents other than minor changes shall be reviewed for adequacy, correctness and completeness, prior to approval and issuance. Major changes shall be reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated.

SECTION 7
CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

WCS QA is responsible for ensuring and documenting that quality affecting purchased items conform to procurement document QA requirements. WCS inspectors are responsible for inspecting quality affecting items when these items are received on site.

Procurement of quality affecting items and services is controlled to assure conformance with specified technical and QA requirements. These controls include requirements for pre-award evaluations of suppliers' QA programs, annual and/or triennial evaluations, periodic audits/source inspections and surveillance. Suppliers with an approved QA program are placed on the Qualified Suppliers List (QSL). Source inspections and surveillances, as well as, evaluations of received items and services are performed, as needed, upon delivery or completion to ensure requirements specified in procurement documents are satisfied.

PROCUREMENT PLANNING

Procurements shall be planned and documented to ensure a systematic approach to the procurement process exists and supports the contract schedule. Procurement planning shall be utilized for significant procurements as follows:

- Identify procurement methods and organizational responsibilities, including what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.
- Be performed relative to the level of importance, complexity and quantity of the item or service being procured and the supplier's quality performance.
- Include the involvement of WCS QA.

SOURCE EVALUATION AND SELECTION

Supplier selection shall be based on an evaluation, performed before the contract and/or purchase order is awarded, of the supplier's capability to provide items or services in accordance with procurement document (technical and quality) requirements. The WCS functional area needing the procurement shall request that WCS QA evaluate the potential supplier for placement on the WCS QSL. Measures for evaluating and selecting procurement sources are detailed in the applicable QA procedure and include one or more of the following methods for evaluating potential suppliers:

- Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use.
- Evaluation of supplier's current quality assurance records supported by any documented qualitative and quantitative information.
- Evaluation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel and quality assurance program implementation.

SUPPLIER PERFORMANCE EVALUATION

The responsible WCS manager shall establish measures to routinely interface with the supplier and to verify supplier performance. The measures shall include:

- Establishing an understanding between WCS and the supplier of the requirements and specifications identified in procurement documents.
- Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.

- Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements.
- Identifying and processing necessary change information.
- Establishing the method to be used to document information exchanges between purchaser and supplier.
- Establishing the extent of source surveillance and inspection.

The extent of purchaser verifications shall be a function of the relative importance, complexity/quantity of items or services being procured and the supplier's quality performance. WCS verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement. Verifications shall include supplier audits, surveillances or source inspections (or combinations) used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's quality assurance program.

CONTROL OF SUPPLIER GENERATED DOCUMENTS

Supplier generated documents shall be controlled, processed and accepted by WCS in accordance with the requirements established in the applicable procedures. Measures shall be implemented to ensure that the submittal of supplier-generated documents is accomplished in accordance with the procurement document requirements. These measures shall also provide for the acquisition, processing and recorded evaluation of technical, inspection and test data compared against the acceptance criteria.

ACCEPTANCE OF ITEMS OR SERVICES

Methods for accepting supplier furnished material, equipment or services shall include one or more of the following, as appropriate to the items or services being procured:

- Evaluating the supplier certificate of conformance
- Performing one or a combination of source verification, receiving inspection or post-installation test
- Technical verification of the product produced
- Surveillance or audit of the work
- Review of objective evidence for conformance to procurement requirements.

The supplier shall verify that furnished material, equipment or services comply with WCS procurement requirements before offering the items or services for acceptance and shall provide to WCS objective evidence that the items or services conform to procurement documents.

CERTIFICATE OF CONFORMANCE

When a certificate of conformance is used to accept material, equipment or services the following apply:

- The certificate shall identify the purchased items or service to the specific procurement document.
- The certificate shall identify the specific procurement requirements met by the purchased item or service. The procurement requirements identified shall include any approved changes, waivers or deviations applicable to the item or service.
- The certificate shall identify any procurement requirements that have not been met together with an explanation and the means for resolving nonconformances.
- The certificate shall be signed and dated or otherwise authenticated by an individual who is responsible for the supplier's quality assurance function.

SOURCE VERIFICATION

WCS may accept items or services by source verification. Source verification can include monitoring, witnessing or observing activities performed by the supplier. Source verification shall be implemented consistent with the supplier's planned inspections, examinations or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item.

RECEIVING INSPECTION

When receiving inspection is used to accept an item:

- The inspection shall consider any source verifications/audits and the demonstrated quality performance of the supplier.
- The inspection shall be performed in accordance with established inspection procedures.
- The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical and other characteristics; freedom from shipping damage; and cleanliness.
- The inspection shall be planned and documented.
- Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation.

POST-INSTALLATION TESTING

When post-installation testing is used as a method of acceptance, the WCS responsible manager and the supplier shall mutually establish test requirements and acceptance documentation.

CONTROL OF SUPPLIER NONCONFORMANCES

The responsible WCS manager and the supplier shall establish and document the process for disposition of items that do not meet procurement document requirements. The supplier shall evaluate nonconforming items according to the applicable requirements of Section 15 "Control of Nonconforming Items" and submit a report of nonconformance to the responsible WCS manager including supplier recommended disposition (for example, use-as-is or repair) and technical justification. Reports of nonconformances to procurement document requirements, or documents approved by WCS, shall be submitted to the responsible WCS manager for disposition whenever one of the following conditions exists:

- Technical or material requirements are violated.
- A requirement in supplier documents, which have been approved by WCS, is violated.
- The nonconformance cannot be corrected by continuation of the original manufacturing process or by re-work.
- The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

QUALIFIED SUPPLIER LIST

WCS QA is responsible for the development and maintenance of the WCS Qualified Suppliers List (QSL). The QSL contains those suppliers with acceptable Quality Assurance Programs that have been evaluated and accepted by WCS. The WCS QA organization shall perform an evaluation of each supplier of Quality Level 1 items and service every 12 months. Satisfactory results will maintain the supplier on the QSL. Additionally, suppliers of Quality Level 2 items and services will be evaluated at least triennially. Suppliers that have unacceptable evaluations or that have not had a procurement placed with them in 3 years will be removed from the QSL.

SECTION 8
IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

The WCS managers are responsible for ensuring that all applicable material, parts, and components that are quality affecting are properly identified.

Contractors are responsible for establishing procedures to identify and control material, parts, and components, which are used for quality-affecting work or activities. These material, parts, and components include such things as geologic cores, and field and laboratory samples.

The controls necessary to ensure that only correct and accepted items are used or installed will be required by the appropriate QA procedure. Identification requirements for materials, parts and components are stated in design specifications, drawings, and procurement documents.

IDENTIFICATION

Identification on the items shall be established and maintained. Items shall be identified from the time of initial fabrication, or receipt, up to and including installation or end use. The identification shall relate the item to the pertinent specifying document.

Quality affecting geologic and environmental data collected shall include the time and the location of origin. As applicable, identification shall be maintained from collection through shipment and subsequent analysis.

PHYSICAL MARKINGS

Item identification methods shall include use of physical markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (i.e., physical separation, labels or tags attached to containers or procedural control).

Physical markings, when used, shall:

- Be applied using materials and methods that provide a clear and legible identification,
- Not detrimentally affect the function or service life of the item,
- Be transferred to each part of an identified item when the item is subdivided, and
- Not be obliterated or hidden by surface treatments or coatings, or after installation unless other means of identification are substituted.

TRACEABILITY

Item identification methods shall ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents. Item traceability documentation shall ensure that the item can be traced at all times from its source through installation or end use.

OTHER REQUIREMENTS

The controls for items shall address the following requirements, as applicable:

- If codes, standards or specifications include specific identification or traceability requirements (i.e., identification or traceability of the item to applicable specification or grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records), then identification and traceability methods shall implement the requirements specified.
- If items have a limited operating or shelf life specified, then methods shall be established that preclude using the item beyond the shelf or operating life.

- If item storage is required, then methods shall be established for the control of item identification that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:
  - Maintenance or replacement of markings and identification tags damaged during handling or aging,
  - Protection of identification markings subject to excessive deterioration resulting from environmental exposure, and/or
  - Updating related documentation.

SECTION 9
CONTROL OF SPECIAL PROCESSES

Processes are controlled to ensure quality is maintained by utilizing appropriately trained and qualified personnel. WCS employees and contractors are responsible for conducting quality affecting processes in accordance with documented procedures.

SPECIAL PROCESSES

Special processes that control or verify quality shall be controlled according to the requirements of this section whether or not they are covered by existing codes and standards, or whether or not the quality requirements specified for an item exceed those of existing codes or standards.

PERSONNEL, PROCEDURES, AND EQUIPMENT QUALIFICATIONS

WCS procedures shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Each special process shall be performed in accordance with a procedure that includes the following elements as applicable:

- The responsibility of the organization performing the special process to adhere to the approved procedures and processes,
- Qualification requirements for personnel, procedures and equipment,
- Conditions necessary for accomplishment of the special process shall include proper equipment, controlled parameters of the process and calibration requirements, and/or
- Requirements of applicable codes and standards, including acceptance criteria for the special process.

SECTION 10
INSPECTION

Inspections required to verify conformance of an item or activity to specified requirements are planned and executed. Characteristics to be inspected and inspection methods to be used are specified in procedures. Inspection results are documented. Persons other than those who performed or directly supervised the work being inspected shall perform inspection for acceptance.

INSPECTION PLANNING

Inspection planning shall be performed, documented and include:

- Identification of work operation where inspection is necessary to ensure quality and implementing documents that shall be used to perform the inspections;
- Identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed;
- Identification of inspection or process monitoring methods to be employed;
- The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements;
- Identification of the qualification level of personnel performing inspections;
- Identification of acceptance criteria;
- Methods to record objective evidence of inspection results.

SELECTING INSPECTION PERSONNEL TO PERFORM INSPECTION

The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to perform the assigned inspection tasks. Inspector qualifications are documented and maintained current Inspections shall be performed by personnel other than those who performed or directly supervised the work being inspected.

INSPECTION HOLD POINTS

When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization establishing the hold point, the specific hold points shall be identified in work control documents. Consent to waive specified hold points shall be documented and approved before continuing work beyond the designated hold point.

IN-PROCESS INSPECTIONS

Quality affecting items shall be inspected when necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment and personnel shall be provided. Inspection and process monitoring shall be conducted when control is inadequate with only one method. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process. Controls shall be established and documented for the coordination and sequencing of inspections and monitoring at established inspection points during successive stages of the process or construction.

FINAL INSPECTION

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage or other characteristics as required in order to verify the quality and conformance of the item to specified requirements

INSPECTION DOCUMENTATION

Inspection documentation shall include:

- The item inspected, date of inspection, the name of the inspector;
- Results or acceptability;
- Measuring and test equipment if used; and
- Reference to information on actions taken in connection with nonconformances, as applicable.

SECTION 11
TEST CONTROL

Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with acceptance criteria is evaluated. Tests required to collect data, such as for site characterization or design input, shall be planned, executed, documented and evaluated.

WCS Managers are responsible for coordinating the development of test procedures, as required and where appropriate, and for ensuring that contractors implement appropriate test procedures.

TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests are controlled. Test requirements and acceptance criteria are based upon specified requirements contained in applicable design or other pertinent technical documents.

TEST PROCEDURES

Test procedures shall include:

- Test Objectives
- Test Requirements
- Qualifications of Test Personnel
- Selection and Identification of the Measuring and Test equipment
- Acceptance Criteria
- Test Documentation

USE OF OTHER TESTING DOCUMENTS

Other testing documents (e.g., American Society for Testing and Materials (ASTM)) specifications, supplier manuals or other related documents containing acceptance criteria may be used instead of preparing special test procedures.

TEST RESULTS

Test results shall be documented and evaluated by a qualified individual to ensure that test requirements have been satisfied.

TEST RECORDS

Test records shall include:

- Item tested, date of test, names of tester and data recorders, type of observation and method of testing;
- Identification of test criteria or reference documents used to determine acceptance;
- Results and acceptability of the test;
- Actions taken in connection with any nonconformances or deviations noted;
- Name of the person evaluating the test results; and
- Identification of the measuring and test equipment (M&TE) used during the test.

SECTION 12
CONTROL OF MEASURING AND TEST EQUIPMENT

Tools, gauges, instruments, and other measuring and test equipment used for quality affecting activities shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.

WCS managers are responsible for the implementation of the measuring and test equipment procedures and ensuring that calibrated items are used in quality affecting activities.

CALIBRATION

Measuring and test equipment (M&TE) shall be calibrated, adjusted and maintained at prescribed intervals or, prior to use, against reference calibration standards having traceability to nationally recognized standards. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented. Calibration standards shall have a greater accuracy than the required accuracy of the M&TE being calibrated. If calibration standards with a greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used, provided they are shown to be adequate for the requirements. The basis for the calibration acceptance shall be documented. The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use and other conditions affecting measurement control. Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration and uniquely identified to provide traceability to its calibration data.

DOCUMENTING THE USE OF M&TE

The use of M&TE shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected or items inspected or tested since the last calibration.

OUT OF CALIBRATION M&TE

M&TE is considered to be out-of-calibration and not be used until calibrated if any of the following conditions exist:

- The calibration due date or interval has passed without re-calibration.
- The device produces results known or suspected to be in error.

Out-of-Calibration M&TE is controlled. Out of calibration M&TE is tagged or segregated and not used until recalibration.

When M&TE is found out-of-calibration, the validity of results obtained using that equipment since its last valid calibration is evaluated to verify the acceptability of previously collected data, processes monitored, or items previously inspected or tested. If any M&TE is consistently found out-of-calibration during the re-calibration process, it is repaired or replaced.

HANDLING AND STORAGE

M&TE shall be properly handled and stored to maintain accuracy.

COMMERCIAL DEVICES

Calibration and control shall not be required for rulers, tape measures, levels and other normal commercial equipment that provides adequate accuracy

M&TE DOCUMENTATION

M&TE calibration documentation shall include the following information:

- Identification of the measuring or test equipment calibrated;
- Traceability to the calibration standard used for calibration;
- Calibration data;
- Identification of the individual or supplier performing the calibration;
- Date of calibration and the re-calibration due date;
- Results of the calibration and statement of acceptability;
- Reference to any actions taken in connection with out-of-calibration.

SECTION 13
HANDLING, STORAGE AND SHIPPING

Handling, storage, cleaning, packaging, shipping and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration.

WCS is responsible for handling, storage, and shipping controls as provided in Design Specifications. WCS contractors are responsible for ensuring that handling, storage, and shipping activities are adequate and conform to WCS requirements.

CONTROLS

Handling, storage, cleaning, packaging, shipping and preservation of items shall be conducted in accordance with procedures, shipping instructions or other specified documents. For critical, sensitive, perishable or high-value articles, specific instructions for handling, storage, cleaning, packaging, shipping and preservation shall be prepared and used.

SPECIAL EQUIPMENT, TOOLS AND ENVIRONMENTS

If special equipment and environments are used, provisions shall be made for their verification. Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained. Operators of special handling and lifting equipment shall be experienced or trained in the use the equipment.

OPERATORS

Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

MARKING AND LABELING

Measures shall be established for marking and labeling for the packaging, shipping, handling and storage of items as necessary to adequately identify, maintain and preserve the item. Markings and labels shall indicate the need for special controls if necessary.

SECTION 14
INSPECTION, TEST AND OPERATING STATUS

Status is indicated either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated. Status is maintained through indicators (i.e., physical location and tags, markings, shop travelers, stamps, inspection records or other suitable means). The authority for application and removal of tags, markings, labels and stamps are specified. Status indicators shall also provide for indicating the operating status of systems and components of the facility (i.e., tagging valves and switches) to prevent inadvertent operation.

WCS managers are responsible for identifying and implementing any inspection, test, and operating status procedures/instructions that may be necessary. Contractors, if applicable, are responsible for ensuring that inspection, test, and operating status activities are adequate and conform to direction provided by the WCS manager.

SECTION 15
CONTROL OF NONCONFORMING ITEMS

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall be provided for the identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items.

WCS employees and contractors are responsible for identifying and reporting nonconforming items. WCS QA is responsible for managing the nonconformance process and concurring with the resolution provided by the WCS managers.

DOCUMENTING AND EVALUATING NONCONFORMING ITEMS

Nonconformance reports shall clearly identify and describe the characteristics that do not conform to specified criteria. Nonconformance reports shall be reviewed by the responsible WCS organization and recommended dispositions of nonconforming items shall be developed. In addition, organizations affected by the nonconformance shall be notified. Recommended dispositions shall be evaluated and approved. The WCS QA organization is responsible for managing the nonconformance process. Further processing, delivery, installation or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition by the responsible WCS manager.

IDENTIFYING NONCONFORMING ITEMS

Nonconforming items shall be identified by marking, tagging or other methods that do not adversely affect their end use. The identification shall be legible and easily recognizable. If the identification of a nonconforming item is not practical, the container, package or segregated storage area, as appropriate, shall be identified.

SEGREGATING NONCONFORMING ITEMS

Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use.

DISPOSITION OF NONCONFORMING ITEMS

The disposition, such as "use-as-is," "reject," "repair," or "rework," of nonconforming items shall be identified and documented. The technical justification for the acceptability of a nonconforming item that has been dispositioned "repair" or "use-as-is" shall be documented. Items that do not meet original design requirements that are dispositioned "use-as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design. If changes to the specifying document are required to reflect the as-built condition, the disposition shall require action to change the specifying document to reflect the accepted nonconformance Any document or record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation; and, when each document or record is changed, the justification for the change shall identify the nonconformance documentation. The disposition of an item to be reworked, or repaired shall contain a requirement to reexamine (inspect, test, or nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be reexamined in accordance with applicable procedures using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

TRENDING

Nonconformance documentation shall be periodically analyzed by the WCS QA to identify quality trends in accordance with Section 16 "Corrective Action."

SECTION 16
CORRECTIVE ACTION

Conditions adverse to quality shall be identified promptly, reported to appropriate levels of management and corrected as soon as practical. Such conditions shall be tracked and evaluated so that adverse trends can be identified and appropriate corrective action can be taken.

QA procedures shall be established to provide requirements and processes for the following activities:

- Prompt identification, correction and trending of all conditions adverse to quality.
- Evaluating significant conditions adverse to quality and determining cause, including corrective actions to prevent recurrence.
- Stopping work, if applicable.
- Verifying implementation of corrective actions.

WCS employees and contractors are responsible for identifying and reporting conditions adverse to quality. WCS QA is responsible for managing the corrective action process and concurring with the corrective action plans provided by the WCS managers.

FOLLOW-UP ACTION

The corrective action process shall include a requirement for WCS management to take follow-up action to verify implementation of corrective action taken to address significant conditions adverse to quality. The WCS QA organization shall be responsible for conducting periodic assessments of these follow-up actions.

TRENDING

Reports of conditions adverse to quality and significant conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify causes. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Identified adverse trends shall be reported to WCS management.

SECTION 17
QUALITY ASSURANCE RECORDS

Records that provide documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

WCS staff and contractors are responsible for preparing, safeguarding, and submitting records to the WCS Records Center. WCS managers are responsible for ensuring that records are complete and submitted to the WCS Records Center. The WCS Records Center is responsible for receiving, designating, validating, and filing quality assurance records.

RECORD MANAGEMENT SYSTEM

WCS shall establish a record management system and WCS Records Center for accomplishing work activities and in compliance with the requirements. The QA record management system shall be described in procedures, instructions or other documentation. Procedures describing the record management system shall include methods for controlling records withdrawn from storage that are required for the completion of work activities.

GENERATION OF QA RECORDS

WCS procedures shall specify the records to be generated and maintained. Documents that are designated to become records shall be legible, accurate and completed appropriate to the work accomplished. Records will be classified for retention purposes as Lifetime or Nonpermanent.

Lifetime records are those that meet one or more of the following criteria:

- Those which would be of significant value in demonstrating capability for safe operation;
- Those which would be of significant value in maintaining, reworking, repairing, replacing or modifying an item;
- Those which would be of significant value in determining the cause of an accident or malfunction of an item; and/or
- Those, which provide required baseline data for in-service inspections.
- Other records as required to satisfy regulatory requirements and business purposes.

Lifetime records are required maintained for the life of the particular item while it is installed in the facility or stored for future use.

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. QA audits and surveillance reports are examples of nonpermanent records.

Individuals creating records shall ensure the records are legible, accurate and complete, and shall protect them from damage, deterioration or loss during the time the records are in their possession.

Documents shall be considered valid records only if authenticated (i.e., reviewed, initialed, signed and dated by responsible personnel).

RECEIVING QA RECORDS

Records shall be indexed to ensure retrievability. Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item or activity to which it applies. The indexing system shall include:

- The location of the records within the records management system;
- Identification of the item or related activity to which the records pertain.

STORING AND PRESERVING QA RECORDS

Records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

- Natural disasters such as wind, floods or fires;
- Environmental conditions such as high and low temperature and humidity;
- Infestation of insects, mold and rodents;

The WCS records facility shall meet requirements specified in ASME NQA-1, 1994 Edition, Section 17 "QA Records", supplement 17S-1 "Supplemental Requirements for QA Records", Section 4.4 "Storage Facilities."

Dual facilities, containers shall be provided for records storage if a single facility, container or combination thereof is not capable of providing adequate protection.

RETENTION OF QA RECORDS

Lifetime records shall be retained and preserved for the operating life of the item or facility. Nonpermanent records shall not be disposed of until the following conditions are met:

- Regulatory requirements are satisfied;
- Facility status allows document disposal; and
- WCS QA requirements are satisfied.

SECTION 18
AUDITS, SURVEILLANCE AND ASSESSMENT

WCS shall utilize QA audit, QA surveillance and assessment to verify compliance with all aspects of the QA Program. QA audits represent the formal documented process of verification as described in this section. QA surveillance is less formal and does not require a schedule, plan or checklist and can be conducted by a qualified QA employee. Surveillance results are documented. Assessments are conducted by the WCS line organizations for the purpose of self-identification of issues and performance improvement. The assessment process includes an annual management review of the QA Program effectiveness.

WCS QA is responsible for establishing and implementing the audit and surveillance program. Lead auditors, auditors, and technical specialists are responsible for conducting audits.

The WCS QA audit process is responsible for ensuring that facility performances defined in 30 TAC 336.723 and the technical environmental analyses provided in 30 TAC 336.709 are accomplished. The audit process will validate if inspections or surveillance are used to verify results.

Audited organizations are responsible for reviewing audit and surveillance results and developing corrective actions as necessary. WCS QA shall verify compliance with elements of the WCS QA Program and determine QA Program effectiveness by ensuring that planned and scheduled audits are conducted. Elements that have been selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively.

AUDIT SCHEDULES

Internal or external audits shall be scheduled in a manner to provide coverage, consistency and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work. An audit schedule shall be developed and revised as necessary to ensure that coverage is maintained.

AUDIT PLANS

An audit plan shall be developed for each audit. This plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used.

AUDIT TEAMS

WCS QA shall assign auditors who are independent of any direct responsibility for performing the work being audited. The auditors shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. The audit team should include one or more auditors comprised of representatives from the WCS QA organization and if applicable, technical organizations. A lead auditor shall be appointed to supervise the team, organize and direct the audit, prepare and coordinate issuance of the audit report and evaluate responses. Technical specialists may be used to assist in assessing the adequacy of technical processes. Before commencing the audit, the lead auditor shall ensure the personnel assigned to the audit team are prepared and collectively have experience and/or training commensurate with the scope, complexity or special nature of the work to be audited.

AUDIT PERFORMANCE

WCS QA shall provide notification of a planned audit to the affected organizations at a reasonable time before the audit is to be performed. The notification should include all relevant information pertaining to the audit, such as schedule, scope and names of audit lead and team members, if known. In addition, the audit team leader shall ensure the following is performed.

- The audit team shall prepare before starting the audit.
- Audits shall be performed in accordance with procedures or checklists.
- QA program elements that have been selected for the audit shall be evaluated against specified requirements.
- Objective evidence shall be examined to the depth necessary to determine if the selected elements are being implemented effectively.
- Audit results shall be documented and reported to management.
- Identified audit findings shall be documented and the audited organization shall correct the findings according to the requirements of Section 16, "Corrective Action."

REPORTING AUDIT RESULTS

The audit report shall be prepared and signed by the audit team leader and issued to the management of the audited organization in a timely manner after completion of the audit.

The audit report shall include the following information:

- A description of the audit scope.
- Identification of the auditors.
- Identification of persons contacted during the audit.
- A summary of audit results and the documents reviewed, persons interviewed and the specific results of the reviews and interviews.
- Statement as to the effectiveness of the implementation of the QA Program elements audited.
- A description of the adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.
- A requested date for response by the audited organization.

RESPONDING TO AUDITS

Management of the audited organization or activity shall:

- Investigate adverse audit findings in a timely manner;
- Determine and schedule corrective action, including measures to prevent recurrence;
- Prior to or by the requested response date, notify the WCS QA of the actions taken or scheduled, according to the requirements of Section 16 "Corrective Action."

EVALUATING AUDIT RESPONSES

The adequacy of corrective actions for adverse audit findings (conditions adverse to quality) shall be evaluated by WCS QA. When corrective actions are considered inadequate, notification of this determination shall be provided to the audited organization with a request for a revision to the corrective action plan.

CLOSING AN AUDIT

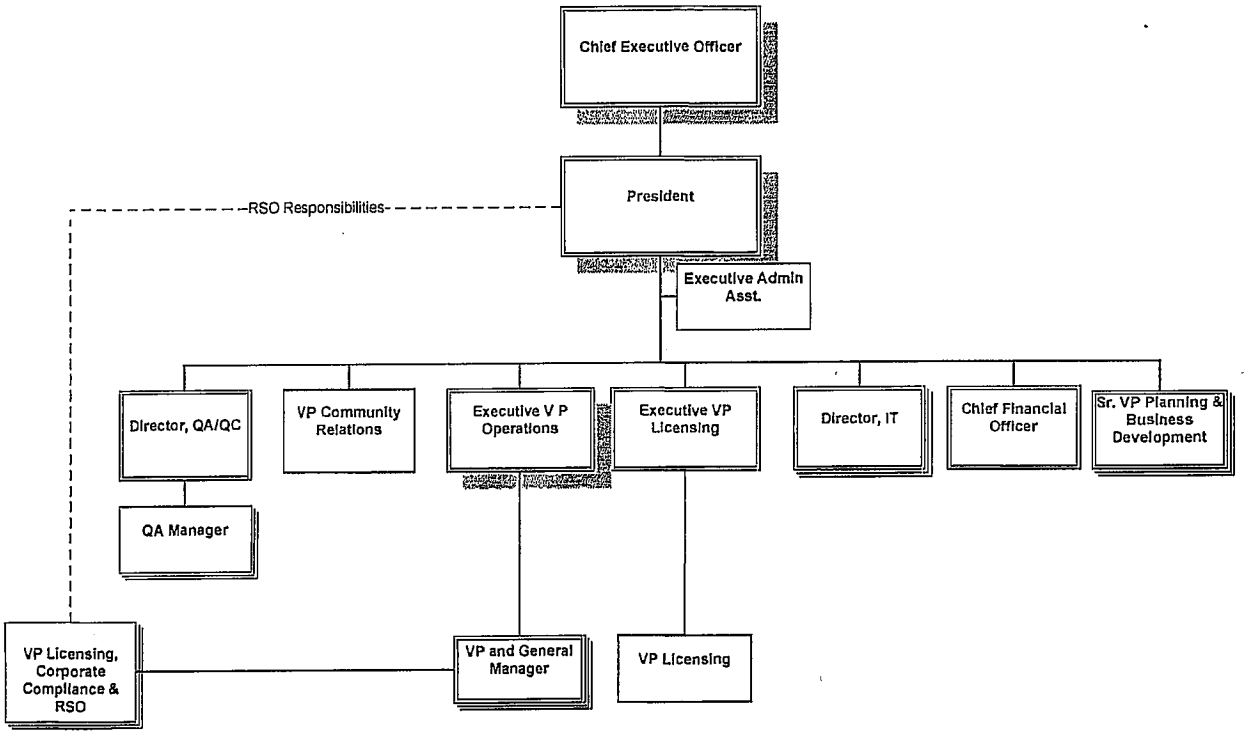
Follow-up action shall be taken by WCS QA to verify that corrective actions are accomplished as scheduled according to the requirements of Section 16 "Corrective Actions." Notification of audit closure shall be provided upon verification that all corrective actions have been satisfactorily completed.

Audit records shall include audit plans, audit reports, written replies and the reference to completed corrective actions.

AUDIT PERSONNEL

Qualified personnel that do not have responsibility for the activity being audited are responsible for conducting audits. Audit personnel performing quality affecting activities shall be certified in accordance with WCS procedure requirements. ASME NQA-1 shall be used as guidance for documenting the qualification of auditors.

CHART 1. WCS ORGANIZATIONAL CHARTS



QUALITY PLANNING

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/1/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda J Beach	2/1/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose of this Quality Planning procedure is to provide instructions for using a graded approach to application of quality assurance (QA) requirements to quality-affecting items and activities. This procedure requires that QA requirements applicable to specific work projects be determined during work planning and specified in a Quality Assurance Project Plan document.

This procedure:

- Establishes the classification criteria for assignment of the appropriate quality level (QL) to WCS structures, systems, components (SSC's), and work activities
- Defines how QL classification is used to determine general applicability to QA Program requirements
- Specifies the grading process to be used for determination of the specific elements of the QA program to be applied during the project
- Provides the methodology for preparation of a QA Project Plan defining the applicable QA controls for each project

This procedure applies to all projects and contracted work performed at or for WCS.

2.0 DEFINITIONS

2.1 Responsible Manager - The manager of the department or project assigned primary responsibility for the subject work activity.

2.2 Work Project - Contracts received at WCS that manages, processes and disposes waste.

3.0 RESPONSIBILITIES

3.1 The **Responsible Manager** is responsible for:

3.1.1 Performing a detailed analysis of project attributes and schedule as necessary to:

3.1.1.1 Classify the project with the appropriate quality level;

3.1.1.2 Grade the individual elements of the work breakdown structure to determine which QA program elements are to be applied to ensure project requirements are satisfied; and

3.1.1.3 Documenting the determined QA requirements in a Quality Assurance Project Plan.

3.2 The **QA Manager** is responsible for ensuring that pertinent quality assurance requirements are contained in quality planning documents by concurrent review and approval.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

None.

5.0 INSTRUCTIONS

5.1 Classification into Quality Level

5.1.1 Classification of work is the first step to support a graded approach to Quality Assurance controls. The responsible manager, based on project analysis, shall determine the proper Quality Level. In some cases, drawings and specifications may have a Quality Level designated. In these cases the responsible design organization determines the Quality Level. In these cases the responsible manager should validate that the information is correct. The following table defines the Quality Levels.

Table A. Guidance for Classification of Work

Quality Level	Quality Level Basis	Criteria Description	QA Program Applicability
1	Nuclear Safety	Structures, Systems, and Components (SSCs) and related quality-affecting work activities relied on to satisfy facility performance objectives.	Application of work pertinent QA program elements is required.
2	Compliance	SSCs and related work activities not relied on to satisfy facility performance objectives but whose performance may be important for ensuring that WCS compliance, operational, and business goals are achieved.	Application of work pertinent QA program elements is required as determined by WCS management to be necessary to ensure compliance with: regulatory requirements and authorizations; and operational and business goals.
3	None	SSCs and related work activities that are not QL-1 or QL-2.	Application of relevant QA program elements is not required.

5.1.2 Use the criteria descriptions in Table A to classify subject work project as QL-1, QL-2, or QL-3. If necessary, contact the Quality Assurance Manager for assistance.

5.1.3 The following QA program applicability assignment is provided to assist the responsible managers in applying proper QA controls.

Table B. WCS QA PROGRAM APPLICABILITY ASSIGNMENT																	
	ASME NQA-1 Criterion																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
WCS Corporate	x	x	x	x	x	x	x								x	x	X	x
WCS Facility	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	X	x
Site Characterization Contractor			x		x	x						x					X	
Design Contractor	x	x	x		x	x									x	x	X	x
Construction Contractor	x	x		x	x	x	x	x	x	x		x	x	x	x	x	X	
Inspection Contractor	x									x		x			x	x	X	

Criterion	Description
1	Organization
2	Quality Assurance Program
3	Design Control
4	Procurement Document Control
5	Instructions, Procedures and Drawings
6	Document Control
7	Control of Purchased Materials, Equipment & Services
8	Identification and Control of Material, Parts and Components
9	Control of Special Processes
10	Inspection
11	Test Control
12	Control of Measuring and Test Equipment
13	Handling Shipping and Storage
14	Inspection Test and Operating Status
15	Control of Nonconforming Items
16	Corrective Action
17	Quality Assurance Records
18	Audits

5.1.3.1 Quality Assurance Activities

a) Quality assurance program implementation

b) Quality assurance records maintenance

c) Audit and surveillance program

d) Control and resolution of nonconformances

e) Completion and control of special processes

f) Radiation safety program

5.1.3.2 Site Characterization and Monitoring

a) Site characterization activities directly related to analyses (see Note 1):

- Geological interpretations and monitoring
- Hydrological interpretations and monitoring
- Environmental monitoring and data
- Climatological data
- Seismic network monitoring
- Computer software use and development (see note 2)
- Performance assessment

b) Further site investigation activities

- Field research of monitoring system performance objectives
- Trench slope investigation
- Field research of trench engineered caps

Note 1

On-site instrumentation used to measure geotechnical, geochemical, or geohydrological parameters are subject to the Quality Assurance Program. Laboratory procedures related to radiological, geochemical, or geohydrological analyses are likewise subject to the Quality Assurance Program. Field data collection such as field interpretation recordation, chain-of-custody procedures, soil, water, and vegetation collection methods are subject to the Quality Assurance Program.

Note 2

Computer analysis is subject to the Quality Assurance Program. This includes software that is either federal or state agency confirmed software, standardized, off-the-shelf software or developed in-house software that has be validated and verified as required in the WCS QA Program. All software packages must be benchmarked and a copy of the proven code must be maintained in a secure file. A copy of the input must be identified or included in the file and a user's manual, if available, must be included.

Codes used for performance assessment include RESRAD, Version 6.22, developed and controlled by Argonne National Laboratory and HELP, Version 3.07, developed and controlled by the US Army Corp of Engineers.

5.1.3.3 Facility Design and Construction

a) Design of the overburden biobarrier and performance cover

b) Design and specification of the compacted clay liner and red bed clay geology

c) Design and construction of the canister disposal unit drainage system

d) Design and construction of the liners, leak detection, and leachate collection system in the mixed waste disposal units

e) Design and construction of the trench cover system

f) Design and construction of the surface water diversion berm

g) Canister construction and inspection

5.1.3.4 Facility Operation

a) Placement of modular concrete canisters, handling of waste shipment containers, and waste matrix compaction and void elimination

b) Operation of the fire suppression system in quality-related buildings

c) Low-level radioactive waste disposal records

5.1.3.5 Closure

- Design and construction of the final grade and trench cover

5.1.3.6 Post-Closure

- Design and implementation of the post-closure monitoring system

5.2 Grading Project Work Elements

5.2.1 After determination of the proper Quality Level, a determination can be made regarding applicable QA criteria and procedures that will be required to successfully perform the project scope of work. A grading analysis for Quality Level 1 work activities is used to identify the QA controls applicable to design, construction, operations, and decommissioning. The following project characteristics are applicable to the grading analysis for QL-1 work activities:

5.2.1.1 Function and end use

5.2.1.2 Consequence of failure

5.2.1.3 Importance of the data being collected or analyzed

5.2.1.4 Complexity of the design or implementation of the activity

5.2.1.5 Reliability of the associated processes and components

5.2.1.6 Reproducibility of results

5.2.1.7 Uniqueness of the item or service quality

5.2.1.8 Necessity for special controls or processes

5.2.1.9 Degree which functional compliance can be demonstrated through inspection or test

5.2.1.10 Other relevant factor and risk as applicable

5.2.2 For QL-1 projects, the responsible manager shall determine the QA criteria pertinent to the items and activities needed for project implementation.

5.2.3 For QL-2 projects, the responsible manager shall determine the QA criteria necessary to ensure compliance with: regulatory requirements and authorizations; and operational and business goals.

5.2.4 Grading is not applicable to QL-3 items or activities.

5.3 Quality Assurance Project Plan (QAPP)

5.3.1 QAPP Preparation

If the subject work project is a QL-1 or QL-2 project, the responsible manager shall develop and document a QAPP as follows:

5.3.1.1 Review the project requirements and any associated procurement documents as necessary to develop a QAPP using Attachment A, WCS QAPP form QA-2.1-1.

5.3.1.2 Provide the administrative information as indicated on the form.

5.3.1.3 Indicate the project quality level determined above and if needed provide the basis for the QL designation.

5.3.1.4 Indicate the project applicable QA criteria as determined above and provide supplemental applicability remarks.

5.3.1.5 Provide a description of any other QA controls applicable to the project (e.g., regulatory, client, or supplier specified).

5.3.2 QAPP Approval and Processing

5.3.2.1 The responsible manager shall forward the prepared QAPP draft to the QA Manager for concurrence and application of any additional QA controls.

5.3.2.2 The QA Manager shall:

- Review the QAPP draft for adequacy and completeness with regard to the applicable requirements.
- Apply additional QA controls if needed.
- Sign and date the QAPP to indicate concurrence.
- Forward the QAPP to the responsible manager for approval.

5.3.2.3 The responsible manager shall:

- Review the changes if applicable.
- Sign and date the QAPP to indicate approval.
- Forward the approved QAPP to document control for inclusion into the document control system.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.2.1 Form QA-2.1-1, "Quality Assurance Projection Plan"

7.0 REFERENCES

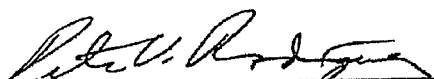
None.

Quality Assurance Project Plan
Form QA-2.1-1

PROJECT NAME:		PROJECT ID #:
◻ CLIENT OR ◻ CONTRACTOR NAME:		CONTRACT ID #:
PROJECT SUMMARY DESCRIPTION:		
QUALITY LEVEL CLASSIFICATION: ◻ QL-1 ◻ QL-2 ◻ QL-3		
BASIS FOR CLASSIFICATION:		
QA PROGRAM CRITERIA APPLICABLE TO PROJECT:		
◻ 1. Organization (Structure)	◻ 10. Inspection	
◻ 2. Quality Assurance Program	◻ 11. Test Control	
◻ 3. Design Control	◻ 12. Control of Measuring and Test Equipment	
◻ 4. Procurement Document Control	◻ 13. Handling, Storage, and Shipping	
◻ 5. Instructions, Procedures, and Drawings	◻ 14. Inspection, Test, and Operating Status	
◻ 6. Document Control	◻ 15. Control of Nonconforming Items	
◻ 7. Control of Purchased Items and Services	◻ 16. Corrective Action	
◻ 8. Identification and Control of Items	◻ 17. Quality Assurance Records	
◻ 9. Control of Special Processes	◻ 18. Audit (or Surveillance)	
CRITERIA APPLICABILITY REMARKS:		
OTHER APPLICABLE QA CONTROLS: (i.e., regulatory or client specified)		
APPROVALS:		
Responsible Manager Name (print)	*Responsible Manager Signature*	*Date*
QA Manager Name (print)	*QA Manager Signature*	*Date*

WASTECONTROL SPECIALISTS LLC	Quality Assurance	Effective Date	QA-2.2
		Revision 1	Page 1 of 2

QA PROGRAM MANAGEMENT REVIEW

PROCEDURE APPROVALS:		
Pete Rodriguez		1/28/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach		2/1/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose and scope of this procedure is to prescribe the process used by Waste Control Specialists LLC (WCS) management to review the status of WCS Quality Assurance (QA) Program adequacy, implementation, and effectiveness.

2.0 DEFINITIONS

None.

3.0 RESPONSIBILITIES

3.1 The **WCS President** is responsible for ensuring that the WCS QA Program is being effectively implemented. This responsibility is executed by appointing an independent Management Review Team Leader and conducting an annual independent management review of the WCS QA Program.

3.2 The **Independent Management Review Team Leader** is responsible for conducting the Management Review and providing a report to the WCS President.

3.3 The **Quality Assurance Director** is responsible for providing documentation and other information as requested by the Review Team.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 Prerequisites, Precautions, and Limitations

The Management Review Team shall be trained to this procedure prior to starting the review.

5.0 INSTRUCTIONS

5.1 Establishing the Management Review Team Leader

1. The President shall:

   a. Appoint a Management Review Team Leader to conduct the review.
   b. Ensure that the Management Review Team Leader is independent of the QA organization.
   c. Determine management review scope and expectations.

5.2 Conducting the Management Review

1. The Management Review Team Leader, based on scope shall:

   a. Select a team to conduct the review.
   b. Assign team responsibilities.
   c. Request needed information from the QA Director.
   d. Ensure the management team reviews the previous year's Management Review Report and provides follow-up on any open items.
   e. Obtain and evaluate QA information provided by the QA Director.
   f. Manage the review team results.
   g. Prepare a Management Review Report and submit the report to the President.

2. The Management Review Report should provide:

   a. Management Review scope.
   b. Areas of review and supporting documents examined.
   c. A statement on the effectiveness of WCS QA Program implementation.
   d. Apparent trends affecting quality.
   e. Any deficiencies identified during the review.
   f. Recommendations and observations, including recommended Corrective Actions.
   g. Narrative addressing review expectations established by the President.

3. The report shall be provided to the President for review, assignment of corrective actions, and approval.

4. The approved report shall be transmitted to the WCS VP/General Manager and Quality Assurance for review and action.

5. QA shall manage all identified deficiencies under the Corrective Action Procedure and observations/recommendation, shall be tracked to closure.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

Management Review Report

7.0 REFERENCES

7.1 WCS QA Plan

WASTECONTROL SPECIALISTS LLC	Quality Assurance	Effective Date	QA-2.3
		Revision 1	Page 1 of 2

TRENDING OF QUALITY ASSURANCE AND QUALITY CONTROL DATA

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/1/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda J Beach	2/1/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose of this procedure is to provide requirements for analysis and trending of Quality Assurance/Quality Control (QA/QC) data generated as a result of implementing the Waste Control Specialists LLC (WCS) QA procedures.

At a minimum, this trending data shall include causal analysis parameters associated with significant corrective actions, nonconforming items, audit and surveillance results, and inspection and testing collected during the implementation of the QA Program.

2.0 DEFINITIONS

None.

3.0 RESPONSIBILITIES

3.1 The **WCS QA Manager** is responsible for implementing the requirements provided in this procedure.

3.2 **WCS Managers** are responsible for investigating the trends and taking appropriate actions.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 Prerequisites

None.

4.2 Precautions and Limitations

None.

5.0 INSTRUCTIONS

5.1 The WCS QA Manager shall systematically monitor QA/QC data and prepare a periodic trend report. Unfavorable trends shall be promptly reported to management. Taproot© causal codes may be used for data points.

5.2 The QA Manager shall examine the data and determine if trends exist. Trends should be categorized as "Emerging Trend," "Adverse Trend," or "No Trend Identified."

5.3 Emerging trends are indicators that an adverse trend could develop. Emerging trends should be investigated by the impacted managers and corrective action applied, if needed.

5.4 Adverse trends are significant conditions that recur on a frequent basis. An adverse trend can be on a process, a procedure, a specific area, or a work crew. Adverse trends shall be investigated by the impacted manager and, if determined to be valid, a Corrective Action Report should be initiated in accordance with WCS Procedure QA-16.1, "Corrective Action Management," which will manage the resolution of the adverse trend.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records;" and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

7.0 REFERENCES

7.1 WCS Procedure QA-16.1, "Corrective Action"

7.2 WCS Procedure QA-17.1, "Quality Assurance Records"

WASTECONTROL SPECIALISTS LLC	Quality Assurance	Effective Date	LL-QA-3.2
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DESIGN CONTROLS FOR CONTRACTORS

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete V Rodriguez	2/5/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda J Beach	2/5/10
VP/GENERAL MANAGER (printed name)	VP/GENERAL MANAGER (signature)	DATE

1.0 PURPOSE AND SCOPE

This procedure establishes requirements and guidance for Waste Control Specialists LLC (WCS) managers securing and managing design contractors tasked to perform final quality-affecting design work.

2.0 DEFINITIONS

2.1 License Application Final Design – A design that was prepared under the controls of a Quality Assurance (QA) program that meets the guidance provided in NUREG-1293 "Quality Assurance Guidance for a Low-Level Radioactive Waste Disposal Facility" and WCS QA requirements. The design is designated for license application review and approval.

2.2 Pre-Construction Design – A design that is designated released for fabrication and construction that has had the design inputs and analyses re-verified as valid and correct.

2.3 Design Input – Those criteria, parameters, bases, or other design requirements upon which a design is based.

2.4 Design Output – Drawings, specifications and other documents used to define technical requirements of structures, systems and components.

2.5 Design Process – Technical and management processes that commence with the identification of design input and that lead to the issuance of design output documents.

2.6 Design Change – Any revision or alteration of the technical requirement defined by approved and issued design output documents.

2.7 Responsible WCS Manager – The manager charged with procuring and managing a quality affecting design contractor.

3.0 RESPONSIBILITIES

3.1 The **Responsible WCS Manager** is responsible for implementing the requirements provided in this procedure.

3.2 The **WCS QA Manager** is responsible for ensuring that WCS contractors providing quality-affecting design services have a QA program and procedures that meet WCS QA requirements.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 Prerequisites

The design contractor's QA program shall be approved prior to start of final quality affecting design activities.

4.2 Precautions and Limitations

None.

5.0 INSTRUCTIONS

5.1 General

Responsible WCS managers and augmented design support staff participate in the design process working under the control of the design contractor's QA Program. The defined areas of design interface include the following:

- Contract Management
- Providing Design Inputs
- Verification Reviews
- QA Audits and Surveillance
- Change Control After Design Approval

5.2 Contract Management

5.2.1 The Responsible WCS Manager shall procure quality-affecting design services in accordance with QA-4.1, "Procurement Document Control".

5.2.2 The Responsible WCS Manager procuring quality-affecting design services shall impose the applicable requirements provided in the WCS QA Plan, Section 3, "Design Control."

5.2.3 The WCS QA Manager shall review the contractor's QA Program and verify that the contractor's QA Program is acceptable for the contracted scope of work.

5.3 Providing Design Inputs

5.3.1 The Responsible WCS Manager and augmented staff (i.e., Cook Joyce Inc., Intera) shall provide design inputs to the design services contractor (i.e., URS Corporation). Typical inputs include:

- Codes and Standards
- System Performance Objectives
- Site Characterization Data
- Operational Features

5.3.2 Changes to design inputs shall be processed in the same manner as the original input.

5.4 Verification Reviews

5.4.1 The Responsible WCS Manager and augmented staff (Cook Joyce and Intera) shall participate in design reviews to ensure correct application of all design inputs.

5.4.2 Design reviews shall be conducted under the controls of the design service contractor's QA program.

5.5 QA Audits and Surveillance

5.5.1 QA verification of the contractor's quality assurance program is performed in accordance with QA-18.1, "QA Audits." Surveillances can also be utilized to verify contractor performance.

5.6 Change Control After Design Approval

5.6.1 When a change is requested to an approved design document (drawing or specification), form LL-QA-3.2-1, "Design Change Request," shall be completed and submitted to WCS Licensing for evaluation.

5.6.2 WCS Licensing shall evaluate the requested change and determine if the requested change impacts the licensed design.

5.6.3 If the requested change impacts the licensed design, an amendment shall be promptly processed with the regulatory authority. The change cannot be processed until authorization is received from the regulatory agency.

5.6.4 WCS Licensing shall document acceptance on form LL-QA-3.2-1 and promptly notify the design service contractor to initiate the changes. The changes shall be processed under the design service contractor's QA program.

5.6.5 If the requested change does not impact the licensed design, WCS licensing shall document acceptance on form LL-QA-3.2-1 and promptly notify the design service contractor to initiate the changes. The changes shall be processed under the design service contractor's QA program.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.2.1 Form LL-QA-3.2-1, "Design Change Request".

6.2.2 QA Audit and Surveillance Reports.

7.0 REFERENCES

7.1 NUREG-1293, "Quality Assurance Guidance for a Low-Level Radioactive Waste Disposal Facility"

7.2 WCS Procedure QA-4.1, "Procurement Document Control"

7.3 WCS QA Plan, Section 3, "Design Control"

7.4 WCS Procedure QA-18.1, "Audits"

7.5 WCS Procedure QA-17.1, "QA Records"

REQUESTED DESIGN CHANGE

DESCRIPTION OF REQUESTED DESIGN CHANGE: ☐ SEE ATTACHED DESCRIPTION

REQUESTOR NAME (print)	REQUESTOR TITLE	REQUESTOR SIGNATURE	DATE

DESIGN CHANGE EVALUATION (WCS LICENSING & REGULATORY AFFAIRS ONLY)

DOES THE REQUESTED DESIGN CHANGE IMPACT THE APPROVED LICENSED DESIGN?

☐ NO	If "NO", proceed to the "Notification of Design Services Contractor" section below to initiate the requested change(s):
☐ YES	If "YES", indicate the affected license section and specific commitment below and then initiate a license amendment as needed.

AFFECTED LICENSE SECTION AND SPECIFIC COMMITMENT: ☐ NA

AMENDMENT REQUEST DATE: ☐ NA	AUTHORIZATION DATE: ☐ NA	LICENSE SECTION AMENDED: ☐ NA	AMEND. #: ☐ NA
EVALUATOR NAME (print)	EVALUATOR TITLE	EVALUATOR SIGNATURE	DATE

NOTIFICATION OF DESIGN SERVICES CONTRACTOR

CONTRACTOR COMPANY NAME	PERSON NOTIFIED	NOTIFIED BY	DATE

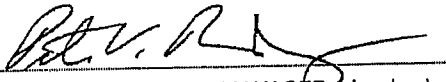
CHANGE VERIFICATION AND CLOSE OUT (WCS LICENSING & REGULATORY AFFAIRS ONLY)

The above requested design changes have been made in accordance with WCS Procedure QA-3.2 and all design documents/drawings affected by these changes have been completed or revised appropriately.

NAME (print)	TITLE	SIGNATURE	DATE

WASTECONTROL SPECIALISTS LLC	Quality Assurance	Effective Date	QA-4.1
		Revision 1	Page 1 of 5

PROCUREMENT DOCUMENT CONTROL

PROCEDURE APPROVALS:		
Pete Rodriguez		1/28/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach		2/1/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose of this procedure is to ensure that approved Waste Control Specialists LLC (WCS) procurement documents specify or reference applicable requirements. Pursuant to application of the quality assurance guidance found in criteria four (4) of ASME NQA-1 and NUREG-1293, this procedure applies to: procurement of quality-affecting items and services as pertinent and commensurate to procurement, scope of work and/or supply and complexity and/or importance of items or services procured. Additionally, the requirements imposed on suppliers by procurement documents provide WCS managers with criteria needed to determine the acceptability of supplier services and items.

For purposes of this procedure:

2.0 DEFINITIONS

2.1 Responsible Manager - The manager of the department or project assigned responsibility for the subject procurement.

2.2 Supplier - Any individual or organization who furnishes a quality-affecting item or service as specified in a procurement document. Therefore, the term "supplier", as used in this document, may mean any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, etc., and their subtier levels.

2.3 Procurement Document - A contract, purchase requisition, purchase order, drawing, specification, or instruction used to define requirements for purchase of quality-affecting items or services by WCS.

3.0 RESPONSIBILITIES

3.1 The **Responsible Manager** is responsible for:

3.1.1 Procurement planning and procurement document development.

3.1.2 Providing the WCS QA Manager with the information and documentation needed for evaluation of the supplier's QA program.

3.1.3 Managing the technical execution of the contract including changes to procurement documents.

3.2 The **Chief Financial Officer** is responsible for developing and managing the commercial requirements for the services being procured and financial relationship with the supplier.

3.3 The **QA Manager** is responsible for ensuring: that pertinent quality assurance requirements are contained in procurement documents by concurrent review and approval; and evaluation of supplier QA programs.

4.0 PREREQUISITES, PRECAUTIONS, and LIMITATIONS

None.

5.0 INSTRUCTIONS

5.1 Content of Procurement Documents

5.1.1 The Responsible Manager shall ensure that applicable procurements are planned and procurement documents are prepared using the systematic approach specified below. Procurement planning shall take into account the following:

5.1.1.1 Level of importance and/or complexity

5.1.1.2 Timeline required for supplier qualification

5.1.1.3 Work and/or delivery schedule

5.1.1.4 Consequences of supplier nonperformance

5.1.1.5 Quantity and expense of items or services being procured

5.1.2 The Responsible Manager shall ensure procurement documents are prepared to explicitly specify the following information when pertinent:

5.1.2.1 A "Scope of Work" describing the services to be procured and the associated work schedule, and/or item description including the manufacturer's identifiers such as part, catalog, or model number as necessary;

5.1.2.2 All work performed shall comply with OSHA requirements;

5.1.2.3 Design and technical requirements documents (may be incorporated by reference) that the supplier must conform to, including as applicable:

- Specific documents (i.e., drawings, codes, standards, regulations, procedures, or specifications) describing the technical requirements of the items or services to be furnished; and
- Identification of appropriate inspection and testing and requirements including the associated acceptance criteria needed to determine product acceptability and evaluate the supplier's performance.

5.1.2.4 Quality Assurance requirements including:

- The requirement for the supplier to have a QA program consistent with applicable WCS quality requirements and appropriate to scope, nature, importance, and complexity of the service(s) or item(s) to be procured.
- The WCS inspection service contractor for quality-affecting inspections shall be required to meet the following requirements:
  - Inspectors verifying quality-affecting work shall be trained and qualified in the specific inspection process and the quality requirements.
  - Training and qualification processes shall be documented.
  - The QC inspector training shall include: (1) Personnel verifying activities affecting quality are trained and qualified in the principles, techniques, and requirements of the activity being performed; (2) Proficiency tests are given to those personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified; (3) Certificates of qualification clearly delineates (i) the specific functions personnel are qualified to perform and (ii) the criteria used to qualify personnel in each function; and (4) Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining, and/or recertifying as determined by management or program commitment.
  - If the inspection process requires certification as dictated in the technical requirements, the certification shall be provided to WCS.
  - WCS QA will verify that these requirements are satisfied prior to start of quality-affecting inspections.
- WCS contractors that have a defined scope of work that manages quality-affecting special processes such as welding, concrete batching, waste and soil compaction, liner placement and other quality-affecting special processes shall be required to meet the following requirements:
  - Organizational responsibilities, including those for the QA organization, are described for the qualification of special processes, equipment, and personnel.
  - Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.
  - Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.
  - WCS QA will verify that these requirements are satisfied prior to start of the applicable special process.

Note

See WCS QA-2.1, "Quality Planning," for instructions on determining QA requirements by classification and grading.

- The requirement for the supplier to incorporate pertinent WCS requirements into any sub-tier supplier procurement documents.

5.1.2.5 The requirement for the supplier to provide WCS with right of access to the supplier's and subtier supplier's facilities, personnel, and records for purposes of surveillance, inspection, or audit by WCS, or authorized WCS representative(s).

5.1.2.6 Provisions for WCS establishment of witness/inspection hold points beyond which work by the supplier cannot proceed without WCS authorization.

5.1.2.7 Schedule and types of documentation to be submitted to WCS for information, review, approval, or acceptance shall be identified.

5.1.2.8 The requirement for the supplier to obtain advance approval from the responsible WCS manager prior to any deviation from procurement document requirements, or performance of out of scope services. The approval of the WCS QA Manager is required for changes to quality requirements.

5.1.2.9 The requirements for the supplier to immediately notify and provide WCS with a written report upon discovery of conditions adverse to quality including: nonconforming items, deficiencies, and work stoppages. WCS approval of partial and full work releases and disposition of nonconformances is required.

5.2 Review and Approval of Procurement Documents

Prior to contract award or placement of an order, procurement documents shall be reviewed and approved by the responsible parties to ensure that the applicable requirements are clearly specified. Any technical or quality assurance program changes resulting from bid evaluations or negotiations must first be incorporated into the draft procurement documents. Procurement approvals shall be documented.

Note

Concurrent requirements for supplier and bid evaluation and supplier selection shall be met in accordance with "Control of Purchased Items and Services" before procurement approval.

5.2.1 The Responsible Manager shall review procurement documents to ensure that they meet all of the applicable requirements described in the "Content of Procurement Documents" section above. As appropriate and prior to approval, the Responsible Manager shall obtain concurrent acceptance of the procurement documents from any supporting technical organization and/or appropriate WCS management. Upon

approval, the Responsible Manager shall forward the procurement documents to Quality Assurance.

5.2.2 Quality Assurance shall review the procurement documents to determine if the stated QA requirements are acceptable. If the procurement documents are not acceptable QA will return the documents for correction and resubmission. If acceptable, QA will approve the documents and forward them to the purchasing organization for processing the procurement.

5.3 Procurement Document Changes

Procurement document changes affecting technical or quality requirements shall be subject to the same requirements described above.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, Quality Assurance Records; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

Documents created to procure quality-affecting items and/or services.

7.0 REFERENCES

7.1 WCS Quality Assurance Plan

7.2 NUREG-1293: Quality Assurance Guidance for a Low-Level Radioactive Waste Facility

7.3 ASME NQA-1: American Society of Mechanical Engineers, Quality Assurance Program Requirements for Nuclear Facilities

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete V. Rodriguez	1/25/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda J Beach	1/26/10
VICE PRESIDENT/GENERAL MANAGER *(printed*	VICE PRESIDENT/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose of this procedure is to ensure that quality-affecting activities are prescribed by and performed in accordance with controlled Standard Operating Procedures and/or Work Instructions. This procedure establishes WCS controls for preparation, review, approval, implementation, and control of Standard Operating Procedures (SOPs) and/or Work Instructions (WIs).

2.0 DEFINITIONS

2.1 Responsible Manager – The manager of the department or project assigned primary responsibility for the subject work activity covered by the SOP or WI.

2.2 Quality Affecting Work – Work classified as Quality-Level 1 (QL-1) and Quality-Level 2 (QL-2) according to Section 2 of the WCS Quality Assurance Plan and QA-2.1, Quality Planning.

2.3 Minor Change – A change to an SOP or WI that does not significantly modify the intent, requirements, or responsibilities specified in the document.

2.4 Blue Sheeting - A process method that is used to make global changes to SOP/WIs.

3.0 RESPONSIBILITIES

3.1 All WCS employees are responsible for:

3.1.1 Performing work in accordance with the prescribed SOPs and/or WIs; and

3.1.2 Reporting any identified deficiencies in SOPs (or WIs) and prescribed work processes to the Responsible Managers and the QA Manager.

3.2 The Responsible Manager or delegate is responsible for:

3.2.1 Routinely evaluating work performed within their functional area of responsibility to:

3.2.1.1 Identify quality-affecting work activities; and

3.2.1.2 Ensure that quality-affecting work is accomplished in accordance with an SOP;

3.2.2 Ensuring that SOPs are properly prepared, reviewed, approved, and implemented; and

3.2.3 Performing periodic review and revision of SOPs as necessary to meet any changing requirements and provide for process improvements.

3.3 Vice President/General Manager is responsible for reviewing and approving proposed changes to SOPs as needed to ensure that any SOP revisions do not result in a reduction of administrative controls relied upon to meet licensing commitments.

3.4 Oversight Management is responsible for:

3.4.1 Reviewing SOPs with a focus on ensuring that the work is prescribed in accordance with safe practices and specified requirements pertinent to the reviewer's assigned organizational span of authority and responsibility.

3.5 The Quality Assurance Manager is responsible for:

3.5.1 Developing, ensuring adequacy, and updating WCS Quality Assurance Procedures;

3.5.2 Providing concurrence review and approval for quality-affecting procedures; and

3.5.3 Performing periodic adequacy and implementation audits of quality-affecting work activities, SOPs and/or WIs.

3.6 The Radiation Safety Officer (RSO) is responsible for:

3.6.1 Approving all Radiation SOPs; and

3.6.2 Performing an annual review of the Radiation Safety affecting SOPs.

3.6.3 Ensuring that SOP revisions do not result in a reduction of radiation safety controls.

3.7 The Procedure Administrator or Records Administrator is responsible for:

3.7.1 Providing Responsible Managers with administrative support as needed in implementing this procedure;

3.7.2 Ensuring that only the most current revision of each SOP is available on the WCS network for use; and

3.7.3 Maintaining a master file containing the revision history and all revisions, for each SOP and WI,

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS:

None.

5.0 INSTRUCTIONS

5.1 Quality-Affecting Work Identification

The Responsible Manager shall routinely evaluate work performed within their functional area of responsibility to: (a) identify quality-affecting work activities; and (b) ensure that quality-affecting work is controlled and accomplished in accordance with an SOP as described below.

5.2 SOP Preparation and Content

5.2.1 SOP Identification Number:

Each Standard Operating Procedure shall be assigned an alphanumeric identification number as follows:

5.2.1.1 Assign a prefix of LL if the procedure is only applicable to the Low Level Facility operations. If the procedure is applicable to all WCS facilities and work activities, the prefix is not required

5.2.1.2 Add a hyphen.

5.2.1.3 Add two (2) or three (3) alphabetical characters to reference the responsible department or project (i.e., RS for Radiological Safety or OP for Operations).

5.2.1.4 Add a hyphen.

5.2.1.5 Assign a sequential number or set of numbers separated by a decimal point(s), as needed to ensure each procedure is assigned a unique ID number. When useful, these numbers should be assigned based on individual functions within the department (e.g., LL-RS-2.X.Y for exposure monitoring procedures & LL-RS-3.X.Y for radiological instrument operation procedures).

5.2.2 SOP Header

Each page of each SOP shall have a header that includes the:

5.2.2.1 WCS Logo;

5.2.2.2 Department Name (may be omitted);

5.2.2.3 SOP Title: The procedure title shall adequately describe the covered operation, process, or activity in a manner precluding confusion with non-applicable activities;

5.2.2.4 SOP ID Number: Assigned by the responsible manager per 5.2.1 above;

5.2.2.5 SOP Revision Number: Beginning with "0" for the first issue, and assigned sequentially afterward;

5.2.2.6 Effective Date: Defined as the date of posting the document for use on the server and/or in a controlled document location; and

5.2.2.7 Page Number: In "X" of "Y" format.

5.2.3 SOP/WI Approvals

5.2.3.1 SOPs and WIs shall have a Procedure Approvals Block below the First Page Header and above the Purpose and Scope (Section One). The Approvals Block format shall be as shown below the First Page Header of this procedure.

5.2.3.2 The Responsible Manager shall coordinate the review and resolution of comments, and obtain approvals from members of WCS management with direct and oversight responsibilities for work prescribed by the SOP/WI.

NOTE

Obtaining a general review and comment from other personnel, such as affected supervisors and workers, or subject-matter-experts is recommended.

5.2.3.3 Reviews shall include a comparison of the pertinent governing (upper-tier) requirements to the requirements for the specific elements of the SOP/WI that are within the reviewer's span of authority and responsibility.

5.2.3.4 The Responsible Manager's, Operations Manager's, and Vice President & General Manager's, or other responsible management reviews should include assessment of the adequacy of the overall work process prescribed in terms of safety, compliance, effectiveness, attention to detail, and efficiency.

5.2.3.5 The RSO's approval shall be obtained for any SOP/WI or changes that may potentially affect Radiation Safety commitments. The RSO shall review SOPs and WIs to ensure license requirements are properly addressed and sound As-Low-As-Reasonably-Achievable (ALARA) principles are applied to process engineering controls, administrative controls, and personal protective equipment.

5.2.3.6 The Health, Safety and Security Director and the Environmental Director or delegates shall review and approve SOPs and WIs to ensure that the work is prescribed in a safe and environmentally compliant manner respectively.

5.2.3.7 The Vice President/ General Manager shall review and approve proposed changes to regulator approved SOPs as needed to ensure that SOP revisions:

- Do not reduce radiation safety or administrative controls;
- Will not result in failure to adequately address licensing commitments; and
- Are placed on hold whenever required or appropriate until regulator approval is obtained.

5.2.3.8 All SOPs and WIs determined to be quality-affecting require the QA manager's review and acceptance.

5.2.3.9 SOP and WI review and acceptance shall be authenticated in Approval Block by recording the approving individual's: printed title and name (preferably typed in); and the written signature and date of approval per 5.2.3.1 above.

5.2.4 SOP Sectioning Format

5.2.4.1 SOP sections should follow the following standard format:

Section#	Section Title
1.0	Purpose and Scope
2.0	Definitions
3.0	Responsibilities
4.0	Prerequisites, Precautions, and Limitations
5.0	Instructions
6.0	Records
7.0	References

NOTE
A Table of Contents is optional.

5.2.4.2 Deviations from standard format may be permitted with the approval of the Vice President & General Manager and the QA Manager.

5.2.5 Description of SOP Sections

Section 1: Purpose and Scope

This section may be written in narrative form with no subsections and shall include a concise description of:

- Purpose: What the procedure is used for, and
- Scope: What specific activities the procedure applies to.

Section 2: Definitions

Provide a statement(s) to explain the meaning of words, phrases, terms, acronyms, etc. used in the procedure.

Section 3: Responsibilities

State the functional title of each person and/or organization with an implementing role specified in the instructions section of the procedure and give a summary description of the assigned responsibility(s) (e.g., The Operations Manager is responsible for...).

Section 4: Prerequisites, Precautions, and Limitations

- Briefly state or reference any conditions that must exist or actions that must be completed, such as required specialized training that must be performed, prior to procedure implementation.
- Identify pertinent special precautions (e.g., safety, compliance).
- Identify pertinent limitations, if any.

Section 5: Instructions – Standard Operating Procedure instructions shall adequately:

- State or reference work requirements, hold points and acceptance criteria needed to determine that prescribed results are attained;
- Describe the specific way and sequence the activity shall be performed;
- Specify responsibilities for each step as needed;
- Identify any special equipment, PPE, or rigging that must be used during the operation, process, or task;
- Include notes as needed to clarify instructions or emphasize special safety considerations, etc.;
- Provide for creation of in-process documentation needed to demonstrate that requirements have been met and acceptance criteria have been satisfied;
- Include a level of detail based upon and commensurate with:

- Complexity and importance of the item or activity to facility performance objectives and regulatory compliance;
- Work environment and worker proficiency and capability (e.g., education, training, experience);
- The need to assure acceptable results that are consistent, reliable and reproducible.
- Include reference to applicable forms, illustrations, figures, graphs, or tables;
- Identification numbers for forms shall be the procedure identification number followed by a hyphen and then a number suffix (i.e., LL-OP-1.1.1-1). The suffix numbers shall begin with number one (1) for the first form and the suffix for any additional forms shall be sequential. Forms are considered attachments;
- Each Attachment will be individually identified in the order they appear, and immediately follow the procedure. Each attachment shall begin on a new page; and
- Illustrations, figures, graphs, or tables may be inserted within the procedure or attached as appendices. Appendices shall be alphabetically sequenced as Appendix A, Appendix B, etc.

Section 6: Records

Identify documentation generated during performance of the procedure that must be maintained as a record.

Section 7: References

List any reference documents that may be needed to perform the procedure.

5.3 WCS Work Instructions

WCS Responsible Managers shall ensure preparation of Work Instructions as needed to supplement the implementation of SOPs. Work Instructions:

5.3.1 Shall provide the specific details and sequenced steps needed for executing a work activity in accordance with the applicable SOPs and any additional requirements;

5.3.2 Are especially useful for prescribing how to appropriately accomplish:

5.3.2.1 Unanticipated safety or quality-affecting tasks requiring prompt completion such as non-routine work for which no SOP exists;

5.3.2.2 Cross-function projects where there is an advantage to addressing accomplishment of applicable requirements from multiple SOPs in a single simplified instructional document; and

5.3.2.3 Repetitive tasks when needed to ensure that appropriate safety and/or quality safeguards are specified before work begins and followed during work performance.

5.3.3 At a minimum, shall include and address the following sections and information:

5.3.3.1 Scope of work covered;

5.3.3.2 WI Expiration date (if applicable);

5.3.3.3 Responsibilities;

5.3.3.4 Instructions with sequential work steps that address pertinent safety, ALARA, quality, and compliance requirements;

5.3.3.5 Work acceptance criteria; and

5.3.3.6 QA Records requirements.

5.3.4 Shall be reviewed and approved according to section 5.2.3 above except that the RSO shall perform the review and approval protocol specified in 5.2.3.7 above.

5.4 SOP and WI Implementation

All WCS Managers shall:

5.4.1 Assess and ensure proper implementation of the requirements of SOPs and WIs covering work performed under their authority and/or to meet their assigned responsibilities.

5.4.2 Promptly report identified instances of failure to meet SOPs and WI requirements to the Responsible Manager and QA Manager to ensure that appropriate corrective and preventative actions will be developed and implemented.

5.5 SOP Revisions, excepting minor changes, are subject to the same requirements applied to the original SOP.

5.6 Minor Changes and Blue Sheeting

Minor changes and blue sheeting, as defined in section 2.3 and section 2.4, may be made to SOPs and WIs without processing the change as a full revision. To make minor changes:

5.6.1 Minor changes shall be marked with a vertical line (change mark) in the right-hand margin adjacent to the change.

5.6.2 The Responsible Manager shall obtain approvals from members of WCS management with direct and oversight roles affected by a minor change. These managers are, based on position, normally those indicated in the Procedure Approvals Block as described in section 5.2.3 above.

5.6.3 Approvals for each minor change shall be indicated by initialing and dating the changed document in the margin to the right of the change mark.

5.6.4 The RSO's approval of minor changes shall:

5.6.4.1 Be obtained for all changes with any potential of affecting radiation safety or administrative controls; and

5.6.4.2 Ensure the change does not result in: a reduction in radiation safety or administrative controls; or failure of the SOP or WI to adequately address licensing commitments.

5.6.5 Approval for minor changes is not subject to the approval and concurrence requirements for original or revised SOPs.

5.6.6 Minor changes shall be processed through the Procedure Administrator in accordance with section 5.7.2 below except that;

5.6.6.1 The revision number shall not be changed except to add a lower-case alpha character to the number. The added alpha characters shall begin with "a" and advance in alphabetical order for each minor change for that revision (e.g., Revision 3 will change to Revision 3a for the first minor change, Revision 3b for the second minor change, etc.).

5.6.6.2 The "Issue Date" shall not be changed. The date of the minor change is indicated next to change with the approval initials.

5.6.7 Blue sheets can be used to make global changes to SOPs and WIs when an organizational change in responsibility, position title or procedure title changes.

5.6.7.1 When a blue sheet is needed, the responsible manager shall contact the Procedure Administrator for support in preparing the blue sheet.

5.6.7.2 An example blue sheet with instructions is provided as Attachment A.

5.6.7.3 The blue sheet will be posted with the impacted documents on the WCS network until the blue sheet changes have been incorporated into the impacted documents.

5.6.7.4 The Procedure Administrator will maintain a log of the blue sheets and maintain the status of the blue sheets.

5.7 SOP Control

5.7.1 Upon obtaining the Approval signatures, the Responsible Manager shall provide the Procedure Administrator with the original authenticated SOP or revision document and the electronic text version in MS Word® form.

5.7.2 The Procedure Administrator or Records Administrator shall:

5.7.2.1 Verify SOP and WI completeness, revision number, approvals and formats are correct with respect to the general format requirements described above;

5.7.2.2 Ensure that only the most current version of each SOP and WI is available by personnel performing the work by:

- Retrieving and disposing of all previous versions of the SOP or WI from each applicable controlled document location, if applicable; and
- Posting the newly effective SOP, WI, or their revisions, on the WCS server and in each applicable controlled document location, if applicable.

5.7.2.3 Create, maintain in the records center, and promptly update a Master File (folder) for each SOP and WI containing:

- The original hand-signed (or initialed minor change) documents of all SOP and WI versions and minor changes; and
- A revision history identifying and describing each revision and minor change made to the SOP or WI. At a minimum, the revision history will include the Date Issued, Revision Number, Change Description and Change Requestor.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records;" and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.2.1 All approved and issued SOPs, WIs and revisions; and

6.2.2 The revision history maintained in the master SOP, WI folder for each SOP.

7.0 REFERENCES

7.1 WCS procedure QA-17.1, "Quality Assurance Records"

7.2 Attachment A: Example "Blue Sheet"

Attachment A: Example "Blue Sheet"

WCS BLUE SHEET DC #_____

Section 1

Effective Date:_____

Page 1 of_____

This Blue Sheet Applies to:

☐ All WCS Plans

☐ All WCS Procedures

☐ Individual Documents as specified (Section3)

Section 2

Type of Change ☐ Organization ☐ Position Titles ☐ SOP/WI Titles ☐ Other (*Describe Below*)

Section 3

Document/Manual/Procedure Group Title(s):

Section 4

Description of Changes and any Special Instructions:

Prepared By/Title:_____ **Date:**_____

Approved By/QA Manager:_____ **Date:**_____

Approved By/ VP General Manager:_____ **Date:**_____

PROCEDURE ADMINISTRATOR STATUS ☐ **Closed**

BLUE SHEET FORM INSTRUCTIONS

A Blue Sheet can be used to update documents such as WCS Plans, Procedures and other implementing documents for global or individual changes. The most common change is to address organizational changes including changes in responsibilities due to reorganization and title changes.

In all cases described above, the document will require a revision to close the requested change. The timeliness of revising the document and closing the Blue Sheet will be based on the significance of the change.

1. The WCS individual requesting a Blue Sheet Document Change should identify the requested change, complete the form and bring the requested change to the WCS Procedure Administrator for processing.
2. The WCS Procedure Administrator will bring the Blue Sheet Document Change request to the attention of the Vice President and General Manager.
3. The Vice President and General Manager will evaluate the requested change and if acceptable, authorize the Procedure Administrator to process. If the requested change is not acceptable, return the form to the Procedure Administrator.
4. For acceptable changes, the Procedure Administrator will apply a DC # (Document Change Number) to the Blue Sheet and submit the Blue Sheet to QA for review.
5. The QA Manager will review to ensure that the requested change does not violate a QA program requirement.
6. After all approvals are received, the Procedure Administrator will insert an effective date on the form and forward the Blue Sheet to Document Control for electronic distribution.
7. For unacceptable Blue Sheet requests, the Procedure Administrator shall notify the requester of the status and discard the request.
8. The Procedure Administrator will maintain a log of the Blue Sheet document change numbers and maintain the status as open until revisions are completed to the impacted documents. When revisions have been completed, mark the Blue Sheet as closed.

END OF DOCUMENT

WASTECONTROL SPECIALISTS LLC	Quality Assurance	Effective Date	QA-6.1
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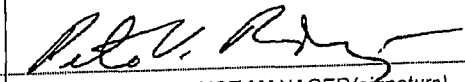
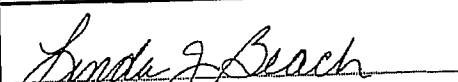
DOCUMENT CONTROL

PROCEDURE APPROVALS:		
Pete Rodriguez		1/28/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach		2/3/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

This procedure describes the Waste Control Specialists LLC (WCS) system for ensuring that correct versions of documents meeting the definition of controlled document are distributed to appropriate personnel, in either hard copy or electronic form, and are available for use.

2.0 DEFINITIONS

None.

3.0 RESPONSIBILITIES

3.1 The **Document Developer/Preparer** is responsible for:

3.1.1 Preparation of procedures and instructions using document format guidelines specified in QA-5.1, "Standard Operating Procedures and Work Instructions".

3.1.2 Submitting approved hard copy and electronic copy, if available, including forms and attachments to Records Administration for processing in accordance with this procedure.

3.2 **WCS staff and contractors** are responsible for using the latest revision of procedures, instructions, drawings and documents in performing quality affecting work activities.

3.3 **Quality Assurance** is responsible for verifying the implementation and effectiveness of document control system during the conduct of audits and surveillance.

3.4 **Records Administration** is responsible for:

3.4.1 Controlling documents that specify quality requirements or prescribe quality affecting activities as provided by Responsible WCS managers and making these documents available to WCS employees.

3.4.2 Maintaining a current listing of controlled documents.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 Prerequisites

None.

4.2 Precautions and Limitations

None.

5.0 INSTRUCTIONS

5.1 WCS managers shall ensure that work assigned to their area of responsibility is performed using the current version of procedures, instructions, drawings and documents. These documents shall be made available at the work location where the work is being performed.

5.2 WCS managers shall submit approved hard copy and electronic copy, if available, including forms and attachments to Records Administration for processing in accordance with this procedure. Documents needing to be placed under document control are transmitted to Records Administration with the distribution list for document holders.

5.3 Before issue or posting of each controlled document, Records Administration shall verify that each controlled document was reviewed and approved in accordance with the governing procedure and is complete and includes a list of attachments.

5.4 Records Administration can make documents available electronically on the WCS Network or by issuing a hard copy to users who request hard copies. Some documents such as drawings may only be available as hard copies and in these cases Section 5.5 -5.7 are applicable.

5.5 Records Administration shall record the submitted documents on the Document Control master list of controlled documents, assign document control numbers, complete transmittal forms and distribute the documents and transmittal form to the document holders.

5.6 Records Administration shall make controlled copies of procedures, instruction, drawings and documents available on the WCS server. Records Administration shall ensure that the master listing of controlled documents is available to document users.

5.7 WCS employees shall return hard copy superseded documents to Records Administration. Hard copy superseded documents shall be marked "uncontrolled".

5.8 Controlled Document Availability; Controlled documents are available on the WCS Network or by making a request at Records Administration.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records;" and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.2.1 Controlled Document Master Listing

6.2.2 Controlled Document Holder Listing

6.2.3 All revisions of controlled documents

7.0 REFERENCES

7.1 Quality Assurance Plan

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SUPPLIER QUALIFICATION

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete V. Rodriguez	1/29/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda D. Beach	2/1/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose of this procedure is to assure, prior to procurement, that prospective suppliers of quality-affecting items or services possess the demonstrated capability to meet Waste Control Specialists LLC (WCS) requirements applicable to the scope-of-supply as specified in the respective procurement documents. A process for supplier evaluation and approval, based on demonstration of supplier capability supported by documented objective evidence, is provided in the instructions below.

WCS Quality Levels are used to apply a graded approach to supplier qualification requirements. WCS Quality Level criteria are found in Section 2 of the WCS Quality Assurance Plan.

This procedure applies to suppliers of Quality Level 1 (QL-1) items and services. Additionally, this procedure applies to suppliers of Quality Level 2 (QL-2) items and services when needed to provide assurance of supplier capability to meet applicable quality, regulatory, and technical requirements.

2.0 DEFINITIONS

2.1 Responsible Manager - The WCS department or project management representative that is primarily and functionally responsible for accomplishing the work that the subject procurement will support.

2.2 Requester - The Responsible Manager's delegate assigned to procure the pertinent item/service.

2.3 Scope-of-supply - The specific items and/or services or category of items and/or services to be procured from the prospective supplier.

2.4 Procurement Documents - Drawings, specifications, statements of work, purchase requisitions, purchase orders, contracts, and/or instructions used to define requirements for purchase, supply and acceptance of supplier items and/or services.

2.5 SQF - Supplier Qualification Form, QA-7.1-1

2.6 QSL - Qualified Supplier List, a listing of suppliers that have been qualified by use of this procedure.

3.0 RESPONSIBILITIES

3.1 The **Responsible Manager** is responsible for:

3.1.1 Ensuring that work planning includes the determination of quality, technical, and regulatory requirements applicable to their procurements;

3.1.2 Documenting the requirements applicable to quality-affecting items and/or services to be procured on the procurement documents and the SQF;

3.1.3 Ensuring that prospective suppliers of quality-affecting items and services are qualified prior to procurement;

3.1.4 Providing QA with sufficient advance notice of the need to perform new supplier qualification and/or expand a previously approved scope-of-supply, such that work schedule is not adversely impacted by the supplier qualification process; and

3.1.5 Completing applicable sections of the SQF as instructed below.

3.2 **Quality Assurance** is responsible for:

3.2.1 Obtaining objective evidence of prospective supplier's quality assurance, technical, and regulatory programs as needed to verify:

- Adequate consistency with respective WCS requirements; and
- Effective implementation of those requirements;
  as pertinent to the planned and specified scope-of-supply.

3.2.2 Evaluation and approval of prospective suppliers.

3.2.3 Ensuring that the QSL is promptly updated and is readily available to all users.

3.2.4 Completing applicable sections of the SQF as instructed below.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 The efficacy of supplier qualification is highly dependent upon the Responsible Manager ensuring accurate determination of the quality, regulatory, and technical requirements that are applicable to the items and/or services to be procured. The Responsible Manager shall determine these requirements during work planning and:

4.1.1 Reference or document the applicable requirements on the SQF and procurement planning documents (statement of work, purchase requisition, etc.) for use in evaluation of supplier capability.

4.1.2 Specify the applicable requirements in the procurement documents such that they are contractually imposed upon the supplier as requirements of supply.

4.2 Supplier evaluation/qualification normally applies to the actual source organization of a particular item but may also apply to distributors when handling and storage requirements (e.g., environmental controls, shelf-life) are required.

5.0 INSTRUCTIONS

5.1 General

5.1.1 Prior to procurement of quality affecting items and services, the Requester shall access and review the WCS QSL as needed to determine the qualification status of the prospective supplier. This review shall include the approved scope-of-supply. If the QSL does not indicate that the supplier is currently qualified to provide the items or services to be procured, the requester shall delay procurement and initiate supplier qualification as instructed below.

Note

Although supplier qualification must normally be complete before procurement of quality-affecting items is permissible, under special circumstances QA may authorize procurement of items before supplier qualification. If prequalification procurement is authorized by QA, then the item must be placed on QA HOLD upon receipt and controlled under QA-8.1, "Identification and Control of Materials, Parts, and Components" to prevent the item from being placed into service until the supplier is qualified.

5.1.2 Supplier qualification shall be performed at a minimum upon:

- Initial supplier qualification;
- Supplier requalification; and
- Expansion of an approved scope-of-supply if the addition of new items and/or services invokes requirements not previously considered in evaluation of the supplier.

5.1.3 A Supplier Qualification Form (SQF) is used to guide and document the qualification process. As appropriate to planned procurements, objective evidence documentation of the supplier's demonstrated capability to meet requirements applicable to the scope of items and/or services to be procured is obtained, evaluated and attached to the SQF.

5.1.4 If a direct evaluation at the supplier's facility(s) is needed to provide documented demonstration of supplier capability, the evaluation report shall be attached to, or referenced on, the SQF.

Note

WCS procedure QA-18.1, "Audits" may be used as guidance for performing and/or documenting direct supplier evaluation.

5.2 Initiation of Supplier Qualification

The Responsible Manager or delegate should initiate qualification of a supplier as follows:

5.2.1 Complete Section 1 of the SQF

Obtain and specify the indicated contact information as available.

5.2.2 Complete Section 2 of the SQF

The Responsible Manager or delegate shall determine and specify the following:

5.2.2.1 Scope-of-supply: The items and/or services or general category of items and/or services applicable to planned procurements from the supplier.

5.2.2.2 Function/Use of Items and/or services to be Procured: What the item will be used for.

5.2.2.3 Applicable Quality Requirements:

a) Specify QL-1 or QL-2 as pertinent to the previously determined "Function/Use of Items and/or services"; and

Note

WCS Quality Level Criteria are found in Section 2 of the WCS QAP.

b) The WCS Quality Requirements (QA Program Elements) applicable to the scope-of-supply with respect to technical and regulatory requirements.

5.2.2.4 Additional Applicable Requirements: Applicable technical, regulatory, and/or WCS mission-objective-based requirements that the supplier must demonstrate the programmatic capability to meet.

Note

If these requirements are pre-specified in draft procurement documents (Statement of Work, Purchase Request, et. al.), simply reference and/or attach these documents.

5.2.3 Forward the initiated SQF to QA.

The SQF may be forwarded as a hand-printed or typed hard-copy or as an e-mail attachment.

5.3 Supplier Evaluation

Quality Assurance shall evaluate the supplier as follows:

5.3.1 Contact the supplier's quality assurance representative and request/obtain objective evidence documentation and records of supplier's programs that are pertinent to applicable requirements.

5.3.2 Evaluate the adequacy and effective implementation of the supplier's applicable programs against the specified applicable requirements.

5.3.3 Qualification/Acceptance Criteria and Response

If the supplier provided documentation provides objective evidence that:

5.3.3.1 All of the applicable elements/attributes of the supplier's programs are adequate and effectively implemented, then the supplier may be fully qualified on the basis of the desktop supplier records evaluation.

5.3.3.2 One or more applicable elements/attributes of the supplier's applicable programs cannot be demonstrated to be adequate and/or effectively implemented by the supplied documentation then either:

a. The supplier qualification status shall be Specifically or Partially Qualified as described below; or

b. A direct evaluation at the supplier's facility is required to demonstrate effective implementation before approval. Notify: the requestor; responsible manager; supplier's representative; and Director of Quality Assurance.

5.3.3.3 Approval from the Director of Quality Assurance and VP/General Manager shall be obtained before performance of each direct supplier evaluation.

5.3.4 Qualification Status

5.3.4.1 A "Fully Qualified" status applies if the supplier was evaluated for a scope-of-supply inclusive of the full range of items and/or services that the supplier provides to all customers.

5.3.4.2 A "Specifically Qualified" status applies if the supplier was evaluated for a scope-of-supply inclusive of only a limited range of items and/or services (as specified in SQF section 2) that the supplier provides to all customers.

> **Note**
>
> Check with the QA Manager before initiation of a qualification needed to expand a scope-of-supply beyond that previously qualified. The previous evaluation may cover the new item/service.

5.3.4.3 A "Partially Qualified" status applies if evaluation shows that only certain elements/attributes of the supplier's applicable programs are adequate and effectively implemented. Indicate the scope of the qualification in the SQF Remarks section.

5.3.5 Re-qualification Frequency and Expiration of Qualification

5.3.5.1 Suppliers of QL-1 items and/or services shall be evaluated at least annually.

5.3.5.2 Suppliers of QL-2 items and/or services shall be evaluated at least triennially.

5.3.5.3 If not re-qualified within one year or three years after the latest qualification for QL-1 and QL-2 item/service suppliers respectively, the supplier's qualifications shall expire and they shall be removed from the QSL.

5.3.6 Complete Section 3 of the SQF based on step 5.3.3 – 5.3.5 determinations above.

5.4 Qualification Approval

The Quality Assurance Manager shall:

5.4.1 Verify that the SQF is properly filled out; the attached documentation demonstrates that the adequacy and implementation of supplier's applicable programs meet the specified requirements; and the documentation packet is complete and assembled into a supplier qualification packet (SQF & attachments);

5.4.2 Document approval of supplier qualification by completion of Section 4 as indicated on the SQF.

5.5 Qualified Supplier List

QA shall:

5.5.1 Ensure that that the QSL is promptly updated when a new approval is received.

5.5.2 Periodically remove expired suppliers from the QSL.

> **Note**
>
> The qualification expiration date is indicated on the QSL.

5.5.3 Provide oversight of the establishment and maintenance of the QSL as needed to ensure prompt availability and update.

5.5.4 Ensure that the following information is included on the QSL: Supplier Name; Responsible Manager; Approved Scope-of-Supply; Qualification Status & status remarks; Qualification Effective Date; Qualification Frequency; and Qualification Expiration Date.

6.0 RECORDS

Completed Supplier Qualification Packets are non-permanent quality assurance records and shall be forwarded to records promptly after SQL data entry.

7.0 REFERENCES

7.1 WCS Quality Assurance Plan (QAP)

7.2 QA-8.1, "Identification and Control of Material, Parts and Components"

SQF SUPPLIER QUALIFICATION FORM

QA-7.1-1

SECTION 1: CONTACT INFORMATION

SUPPLIER NAME :	STREET ADDRESS :	CITY :	STATE :	ZIP CODE :
SUPPLIER QA REPRESENTATIVE NAME :	**PHONE # :**	**FAX # :**	**E-MAIL OR WWW ADRESS :**	
WCS REQUESTER NAME :	**RESPONSIBLE WCS MANAGER :**	**WCS PROJECT OR DEPARTMENT ID :**		**REQUEST DATE:**

SECTION 2: SCOPE, FUNCTION, AND REQUIREMENTS

SCOPE OF SUPPLY *(Specify individual items/services or category of items/services applicable to supplier qualification)* :

FUNCTION/USE OF ITEMS/SERVICES TO BE PROCURED :

APPLICABLE QUALITY REQUIREMENTS : ☐ **ALL 18 ELEMENTS APPLY** | **WCS QUALITY LEVEL :** ☐ QL-1 ☐ QL-2

☐ 1. ORGANIZATION	☐ 7. CONTROL OF PURCHASED ITEMS AND SERVICES	☐ 13. HANDLING, STORAGE AND SHIPPING
☐ 2. QA PROGRAM	☐ 8. IDENTIFICATION & CONTROL OF ITEMS	☐ 14. INSPECTION, TEST AND OPERATING STATUS
☐ 3. DESIGN CONTROL	☐ 9. CONTROL OF SPECIAL PROCESSES	☐ 15. CONTROL OF NONCONFORMING ITEMS
☐ 4. PROCUREMENT DOCUMENTS	☐ 10. INSPECTION	☐ 16. CORRECTIVE ACTION
☐ 5. INSTRUCTIONS, PROCEDURES & DRAWINGS	☐ 11. TEST CONTROL	☐ 17. QA RECORDS
☐ 6. DOCUMENT CONTROL	☐ 12. CONTROL OF MEASURING & TEST EQUIPMENT	☐ 18. AUDITS

ADDITIONAL APPLICABLE REQUIREMENTS *(i.e., technical, regulatory, or WCS mission-objective-based requirements the supplier must meet)* :

SECTION 3: QUALIFICATION BASIS AND STATUS

BASIS	**Desktop Supplier Records Evaluation :** ☐ Program Documents	☐ 3rd Party Certification	☐ 3rd Party Audit
	Direct Evaluation at Supplier Facility: ☐ Inspection / Witness	☐ Surveillance	☐ SQ Audit
STATUS	☐ Fully Qualified *(for full range of items/services offered)*	**Qualification Effective Date:**	
	☐ Specifically Qualified *(just for Scope-of-Supply described above)*	**Qualification Frequency:**	
	☐ Partially Qualified *(for QA elements/attributes described below)*	**Qualification Expiration Date:**	

REMARKS:*(include list of objective evidence documents and any needed explanations or justifications–attach & reference additional remarks if needed)*

SECTION 4: QUALIFICATION APPROVAL

QA MANAGER NAME *(print)* :	QA MANAGER SIGNATURE :	DATE :

QSL DATA ENTRY :	DATE :		BY :	

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/1/10
QUALITY ASSURANCE MANAGER (printed name)	QUALITY ASSURANCE MANAGER (signature)	DATE
Linda Beach	Linda J. Beach	2/1/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

This procedure provides requirements for the identification and control of quality-affecting materials, parts, and components (MPC) to be used in Waste Control Specialists LLC (WCS) Low-Level quality-affecting applications.

2.0 DEFINITIONS

Responsible Manager - The manager of the department or project making use of the quality-affecting MPC.

3.0 RESPONSIBILITIES

3.1 The **Responsible Manager** is responsible for:

3.1.1 Determining and specifying the MPC to be controlled.

3.1.2 Ensuring that WCS and contractors performing quality-affecting installations are in compliance with controls provided in this procedure and the facility technical specifications.

3.2 **All WCS and Contracted Personnel** performing quality-affecting work are responsible for identifying and controlling quality-affecting MPCs with the controls provided in this procedure and the LLW facility technical specifications.

3.3 The **WCS QA Manager** is responsible for auditing the requirements provided in this procedure and documenting the audit results in accordance with QA 18.1, "Audits."

4.0 PREREQUISITES, PRECAUTIONS AND LIMITATIONS

4.1 Prerequisites

Quality-affecting MPC shall be:

4.1.1 Procured in accordance with QA-4.1, "Procurement Document Control" and QA-7.1, "Supplier Qualification".

4.1.2 Inspected upon receipt in accordance with QA-10.1, "Inspections".

4.2 Precautions and Limitations

The Responsible Manager shall ensure that the facility technical specifications have been approved and released for fabrication and construction.

5.0 INSTRUCTIONS

5.1 The Responsible Manager shall review the following LLW facility technical specifications and ensure that the MPC specified in these documents are identified and controlled as stated in the specification and this procedure:

5.1.1 Section 03 30 00, "Reinforced Concrete"

5.1.2 Section 03 40 00, "Precast Concrete"

5.1.3 Section 22 12 00, "Steel Tanks"

5.1.4 Section 22 14 29, "Pumps"

5.1.5 Section 31 05 19.13, "Geotextile"

5.1.6 Section 31 05 19.16, "Geomembrane Liner"

5.1.7 Section 33 46 16.13, "Polyethylene Pipe"

5.1.8 Section 33 46 16.15, "Geocomposite Drain"

5.2 The following attachments to this procedure provide additional instruction and guidance for control of the above MPC in accordance with the referenced specifications:

5.2.1 LL-QA-8.1-1, MPC Control Guide – Reinforced and Precast Concrete

5.2.2 LL-QA-8.1-2, MPC Control Guide – Steel Tanks

5.2.3 LL-QA-8.1-3, MPC Control Guide – Pumps

5.2.4 LL-QA-8.1-4, MPC Control Guide – Geotextile and Geomembrane Liner

5.2.5 LL-QA-8.1-5, MPC Control Guide – Polyethylene Pipe

5.2.6 LL-QA-8.1-6, MPC Control Guide – Geocomposite Drain

5.3 The Responsible Manager shall ensure that identification methods include the use of physical markings. Some of the technical specifications provide specific markings to be applied as required by code or standard. If the physical markings are either impractical or insufficient, other appropriate means shall be used (physical separation and segregation is an example that would be applicable to some concrete materials).

5.4 If physical markings are used, the WCS manager shall ensure that the method used provides clear and legible markings and that the application used for marking does not detrimentally affect the service life of the MPC.

5.5 If a quality-affecting item such as a pipe with code information or a sample with identification has to be divided or split, the WCS manager shall ensure that the required identification is transferred to all subparts of the divided MPC.

5.6 If the technical specifications require that traceability be maintained from manufacture through installation, the WCS manager shall ensure that documents such as travelers are created to ensure conformance to the specifications is documented.

5.7 If MPC are to be stored before use, the WCS manager shall implement measures to:

5.7.1 Ensure the MPC is stored under conditions that conform to the manufacturer's storage instructions and provide for preservation of the pertinent quality-affecting attributes within specification.

5.7.2 Protect the markings that may be subjected to excessive deterioration resulting from environmental damage such as sunlight and rain.

5.7.3 Maintain or replace marking and identification tags that may become damaged or illegible due to handling or aging.

5.8 The WCS QA manager shall audit the implementation of the requirements provided in this procedure. Refer to procedure QA 18.1, "Audits", for details regarding scope and management of audit results.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.2.1 Procurement, certification, and receipt inspection documents.

6.2.2 Travelers and other such documents providing for MPC traceability.

7.0 REFERENCES

7.1 WCS procedure QA-7.1, "Supplier Qualification"

7.2 WCS procedure QA-4.1, "Procurement Document Control"

7.3 WCS procedure QA-10.1, "Inspection"

7.4 WCS procedure QA-17.1, "Quality Assurance Records"

7.5 Technical Specifications of WCS License Application for Near Surface Land Disposal of Low-Level Radioactive Waste:

7.5.1 Section 03 30 00, "Reinforced Concrete"

7.5.2 Section 03 40 00, "Precast Concrete"

7.5.3 Section 22 12 00, "Steel Tanks"

7.5.4 Section 22 14 29, "Pumps".

7.5.5 Section 31 05 19.13, "Geotextile"

7.5.6 Section 31 05 19.16, "Geomembrane Liner"

7.5.7 Section 33 46 16.13, "Polyethylene Pipe"

7.5.8 Section 33 46 16.15, "Geocomposite Drain"

ATTACHMENT A

MPC Control Guide – Reinforced and Precast Concrete *Refer to the controlled copy of Design Specifications 03 30 00 and 03 40 00*	
Control Period	**Control Description**
Procurement	Ensure that identification controls are applied during the procurement process. • Cement – Typically a test report is provided with shipment and accompanies the truck. • Aggregates (sand, stone) – Typically a delivery ticket with the size and type accompanies the truck. • Admixtures and other Additives – Typically a report comes with the shipment that certifies compliance with the specified standard.
Receipt	• Cement – Verify that the cement received is the cement type ordered and matches the test reports provided by the truck driver. Verify that the seals are not broken on the tanker. • Aggregates – Verify that the materials are the materials ordered. Samples will be taken as specified in the design specification. Ensure samples are properly tagged. • Admixtures and other Additives – Verify that the material ordered is the material received. Verify that a Certificate of Compliance or similar documents matches the material received. Concrete materials will be received at the concrete batch plant and placed into storage near the mixer.
Storage	Ensure that the concrete materials are segregated from other non-approved materials, if applicable. Refer to the design specification for other special storage requirements.
Installation	Installation of concrete involves the batching and delivery of the concrete to the concrete placement location. • Batching – Verify that the proper materials are mixed per the approved mix designs. This includes verifying that the proper amounts of materials are mixed. Verify that the delivery ticket denotes the mix number.

	▪ Receipt at placement location – Verify that the proper mix has been delivered by reviewing the delivery ticket. ▪ Test samples will be taken as per the design specification and QC ensures that the test cylinders are properly identified.
QC Inspection	QC inspectors – Verify that the proper concrete mix is delivered and testing has performed and the concrete is acceptable for final placement.

ATTACHMENT B

MPC Control Guide – Steel Tanks *Refer to the controlled copy of Design Specification 22 12 00, "Steel Tanks"*	
Control Period	**Control Description**
Procurement	Ensure that identification controls are applied during the procurement process. Refer to Design Specification Section 22 12 00 "Steel Tanks."
Receipt	Verify that the tank ordered is the tank received and that it is properly labeled with an American Petroleum Institute (API-QI) and an International Organization for Standardization (ISO 9001) registration number.
Storage	Verify that the tank identification is maintained during storage.
Installation	Installer – Verify that the tank identification is correct and installed in the location specified on the design drawings.
QC Inspection	QC – Verify that the tank identification is on the tank and the tank is installed in the proper location as specified on the design drawing.

ATTACHMENT C

MPC Control Guide – Pumps *Refer to the controlled copy of Design Specification 22 14 29, "Pumps"*	
Control Period	**Control Description**
Procurement	Ensure that identification controls are applied during the procurement process. Refer to Design Specification Section 22 14 29, "Pumps."
Receipt	Verify that the pump ordered is the pump received and that it is properly labeled with the manufacturer's name, and that a certificate of compliance is provided with the pump.
Storage	Verify that the pump identification is maintained during storage.
Installation	Installer – Verify that the pump identification is correct and installed in the location specified on the design drawings.
QC Inspection	QC – Verify that the pump identification is on the pump and the pump is installed in the proper location as specified on the design drawing.

ATTACHMENT D

MPC Control Guide – Geotextile and Geomembrane *Refer to the controlled copy of Design Specification 31 05 19.13 and 31 05 19*	
Control Period	**Control Description**
Procurement	Ensure that identification controls are applied during the procurement process. Refer to Design Specification Section 31 05 19.13, "Geotextile" and 31 05 19, "Geomembrane."
Receipt	Verify that the Geotextile and Geomembrane material ordered is the Geotextile and Geomembrane material received at the facility and that it is properly labeled as per the design specifications, and that a certificate of compliance is provided with the material.
Storage	Verify that the Geotextile and Geomembrane material identification is maintained during storage.
Installation	Installer – Verify that the Geotextile and Geomembrane material identification is correct and installed in the location specified on the design drawings. The design specifications contain the installation instructions and controls.
QC Inspection	QC – Verify that the identification is on the Geotextile and Geomembrane material and that the Geotextile and Geomembrane material is installed in the proper location as specified on the design drawing.

ATTACHMENT E

MPC Control Guide- Polyethylene Pipe *Refer to the controlled copy of Design Specification 33 46 16.13*	
Control Period	**Control Description**
Procurement	Ensure that identification controls are applied during the procurement process. All HDPE pipe and fittings shall be in accordance with PE 3408 or equal, and shall conform to ASTM D3350. Refer to Design Specification Section 33 46 16.13, "Polyethylene Pipe."
Receipt	Verify that the polyethylene pipe ordered is the polyethylene pipe received at the facility, that it is properly labeled as per the design specifications, and that a certificate of compliance is provided with the pipe. Pipe identification shall include ASTM D335, size, and schedule.
Storage	Verify that the polyethylene pipe material identification is maintained during storage.
Installation	Installer – Verify that the polyethylene pipe identification is correct and installed in the location specified on the design drawings.
QC Inspection	QC – Verify that identification is on the polyethylene pipe and that the pipe is installed in the proper location as specified on the design drawing.

ATTACHMENT F

MPC Control Guide- Geocomposite Drain *Refer to the controlled copy of Design Specification 33 46 16.15*	
Control Period	**Control Description**
Procurement	Ensure that identification controls are applied during the procurement process. Refer to Design Specification Section 33 46 16.15, "Geocomposite Drain." The geocomposite drain consists of an HDPE geonet with geotextile fused to both sides.
Receipt	Verify that the geocomposite drain material ordered is the geocomposite drain material received at the facility and that the materials are properly labeled as per the design. Verify that a mill test report has been received certifying that the material meets the chemical, physical, and manufacturer's requirements.
Storage	Verify that the geocomposite crain material identification is maintained during storage.
Installation	Installer – Verify that the geocomposite drain material identification is correct and installed in the location specified on the design drawings. The design specifications contain the installation instructions and controls.
QC Inspection	QC – Verify that the identification is on the geocomposite drain material and the geocomposite drain material is installed in the proper location as specified on the design drawing.

WASTECONTROL SPECIALISTS LLC	Quality Assurance	Effective Date	QA-9.1
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SPECIAL PROCESSES QUALIFICATION AND CONTROLS

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/1/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda J. Beach	2/4/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose of this procedure is to establish requirements and controls to ensure that special processes are developed, controlled and accomplished by qualified personnel. This procedure is also used to ensure that equipment and instructions are qualified in accordance with applicable codes, standards and specifications.

The scope of this procedure applies to welding, concrete batching, waste and soil compaction, liner placement and other quality-affecting processes that require controls.

2.0 DEFINITIONS

Special Process – A process, the results of which are highly dependent on control of the process or the skill of the operators, or both, and in which the specified quality control cannot be determined by inspection or test.

3.0 RESPONSIBILITIES

3.1 The **VP/General Manager** is responsible for identifying the special processes that are required to control the work and ensuring that these processes are controlled in accordance with the requirements provided in this procedure. The VP/General Manager is also responsible for developing procurement documents if the special process work will be contracted.

3.2 The **QA Manager** is responsible for verifying the implementation of special process work and verifying that the process instructions are being followed

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 Prerequisites

None.

4.2 Precautions and Limitations

None.

5.0 INSTRUCTIONS

5.1 The VP/General Manager shall review the applicable design documents (drawings and specifications) and identify the special processes required to be controlled. At a minimum, when the scope of work is classified as quality level 1 (QL-1) the following work processes shall be managed as special processes:

- Welding
- Concrete batching
- Waste and Soil Compaction
- Liner placement
- Other processes that meet the definition special processes

5.1.1 The VP/General Manager shall develop procurement documents in accordance with QA-4.1 "Procurement Document Control" to secure a contractor to manage the quality affecting "special process".

5.1.2 The VP/General Manager shall ensure that the procurement documents specify applicable quality and technical requirements, codes, standards and specifications. The VP/General Manager shall also require the contractor meet the following:

5.1.2.1 Organizational responsibilities, including those for the contractor's QA organization, are described for the qualification of special processes, equipment, and personnel.

5.1.2.2 Procedures are required to be established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

5.1.2.3 Qualification records of procedures, equipment, and personnel are established, filed and maintained current.

5.1.3 The QA Manager shall verify that the contractors (suppliers) selected to manage special processes have met the requirements specified in this procedure. This verification shall be documented and maintained in the supplier's QA file.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.2.1 Contractor procedures and the supporting forms generated to implement this procedure are quality-affecting records. The records are maintained by the contractor until these records are transitioned to the WCS QA records center.

6.2.2 Procurement documents are quality affecting records.

6.2.3 QA verification reports of supplier performance are quality affecting records.

7.0 REFERENCES

WCS Quality Assurance Plan

WASTECONTROL SPECIALISTS LLC	Quality Assurance	Effective Date	QA-10.1
		Revision 1	Page 1 of 3
INSPECTIONS			

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/1/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda J Beach	2/4/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose of this procedure is to define the process for preparation and use of Quality Assurance (QA) Inspection Instructions. QA Inspection Instructions are applicable to quality-affecting items and work activities. QA inspections ensure that quality-affecting activities are in conformance with documented instruction, procedures and drawings, etc. This procedure applies to receipt of quality-affecting items.

2.0 DEFINITIONS

2.1 Inspection - Evaluation or examination of an item or activity to verify that it conforms to specified requirements.

2.2 Responsible Manager - The manager of the department or project assigned primary responsibility for the work (item and/or activity) to be completed.

3.0 RESPONSIBILITIES

3.1 The **Responsible Manager** is responsible for:

3.1.1 Determining and specifying process components and items to be inspected.

3.1.2 Providing for development of inspection schedules, characteristics and acceptance criteria.

3.1.3 Requesting and/or procuring the resources necessary to ensure performance of independent inspections.

3.1.4 Ensuring that items and activities within their functional area of responsibility are maintained in a condition conforming to applicable specified requirements.

3.2 The **Inspector** is responsible for:

3.2.1 Conducting assigned inspections in conformance with specified inspection instructions.

3.2.2 Identifying and reporting inspection results and any identified nonconformances.

3.3 The **Inspector's Manager** is responsible for ensuring that personnel performing inspections are qualified and independent of the work being inspected.

3.4 The **QA Manager** is responsible for providing any additional quality requirements not specified by the WCS responsible manager. The QA Manager is responsible for the review and approval

of Inspection Instructions. The QA Manager is responsible for managing inspectors and managing all contracted inspection service contracts.

4.0 PREREQUISITES, PRECAUTIONS AND LIMITATIONS

4.1 Prerequisites

A qualified inspector shall be available and scheduled prior to performance of work or use of the item to be inspected. All inspections are performed by qualified inspectors that report independently to the QA Manager.

4.2 Precautions and Limitations

None.

5.0 INSTRUCTIONS

5.1 The Responsible Manager shall prepare "Inspection Instructions" for quality affecting items and activities. The "Inspection Instructions" shall consider the following types of information, as applicable.

5.1.1 Identifying Information

- Item name and unique number if applicable
- Drawing number and revision level if required to support the inspection
- Supplier name
- Contract or Purchase Order number
- Contractors if used

5.1.2 Inspection Criteria

- Qualification of inspector
- Quality Level for item or activity
- Applicable specifications
- Characteristics of the item to be inspected
- Acceptance criteria
- Mandatory hold points
- Types of M&TE required, including accuracy
- In process inspection points
- Sampling requirements if applicable
- Procurement document requirements (for receiving inspection)
- Reference documents

5.1.3 QA requirements, if pertinent (i.e., supplier certificate of conformance or nondestructive testing).

5.1.4 Documentation

- Inspection reports shall include the item to be inspected, date of inspection, name of inspector, results or acceptability, M&TE used, and reference to any nonconformances identified.
- Inspection Instructions shall be controlled in accordance with QA-6.1 "Document Control." The WCS Responsible Manager is responsible for providing an approved copy of the inspection instructions to document control.

5.1.5 WCS Responsible Managers shall notify the inspector when the specified item or activity is ready for witnessing a hold point or performing the acceptance inspection. When a hold point is established, work shall not proceed beyond the established hold point without the consent of the responsible manager. Waiver of hold point shall be documented by the responsible manager on the inspection documentation.

5.1.6 Inspectors are responsible for conducting inspections in accordance with the approved Inspection Instruction. If the inspection cannot be accomplished as specified in the Inspection Instruction, the inspector shall contact the responsible WCS manager for direction.

5.1.7 Inspectors shall document the results of the inspection in accordance with the forms provided in the approved Inspection Instruction. Inspection results shall be provided to the responsible WCS manager.

5.1.8 The WCS manager shall review the inspection results and if acceptable, forward the inspection results to the WCS records center. If the WCS manager determines that the inspections are not acceptable, the manager shall direct that the work be corrected to meet requirements or the manager can nonconform the completed work in accordance with QA-16.1 "Corrective Action" and have the completed work evaluated for use as is.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements; and

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.1.4 Inspection Instructions

6.1.5 Inspection Results/Records

7.0 REFERENCES

WCS QA Plan

WASTECONTROL SPECIALISTS LLC	Quality Assurance	Effective Date	QA-11.1
		Revision 1	Page 1 of 3
TEST CONTROL			

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/1/10
QUALITY ASSURANCE MANAGER (printed name)	QUALITY ASSURANCE MANAGER (signature)	DATE
Linda Beach	Linda J Beach	2/4/10
VP/GENERAL MANAGER (printed name)	VP/GENERAL MANAGER (signature)	DATE

1.0 PURPOSE AND SCOPE

The purpose of this procedure is to define the process for preparation, performance and documentation of quality-affecting tests. Tests are performed to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service. Required tests include, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests.

2.0 DEFINITIONS

Responsible Manager - The manager of the department or project assigned primary responsibility for performance of the subject testing.

3.0 RESPONSIBILITIES

3.1 The **Responsible Manager** is responsible for:

3.1.1 Coordinating the development of test procedures, as required and where appropriate.

3.1.2 Ensuring that contractors implement appropriate test procedures.

3.2 The **Quality Assurance Manager** is responsible for providing any additional quality requirements not specified by the Waste Control Specialists LLC (WCS) responsible manager.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

None.

5.0 INSTRUCTIONS

5.1 The responsible manager shall prepare test procedures for quality affecting items and activities to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for services. Characteristics to be tested and test methods to be employed are to be specified in test procedures. Test results are documented and their conformance with acceptance criteria is evaluated. Tests required to collect data, such as for site characterization or design input, shall be planned, executed, documented and evaluated.

5.2 Test Procedures shall include the following requirements, as applicable.

5.2.1 Test Objectives;

5.2.2 Test Requirements;

5.2.2.1 Characteristics to be tested; and

5.2.2.2 Test methods

5.2.3 Qualifications of Test Personnel;

5.2.4 Selection and Identification of the Measuring and Test equipment; and

5.2.5 Acceptance Criteria

5.3 Test Documentation

Test documentation shall include:

5.3.1 Item tested;

5.3.2 Date of test;

5.3.3 Names of tester and data recorders;

5.3.4 Type of observation and method of testing;

5.3.5 Identification of test criteria or reference documents used to determine acceptance;

5.3.6 Results and acceptability of the test;

5.3.7 Actions taken in connection with any nonconformances or deviations noted;

5.3.8 Name of the person evaluating the test results; and

5.3.9 Identification of the measuring and test equipment (M&TE) used during the test.

5.4 Other testing documents (e.g., American Society for Testing and Materials (ASTM)) specifications, supplier manuals or other related documents containing acceptance criteria may be used instead of preparing special test procedures.

5.5 The responsible manager shall ensure that test procedures are approved by the organization responsible for the design of the item to be tested unless otherwise designated.

5.6 Test procedures shall be controlled in accordance with QA-6.1 "Document Control". The responsible manager is responsible for providing an approved copy of the inspection instructions to document control.

5.7 Test results shall be documented in accordance with the test procedure and evaluated by the responsible WCS manager that prepared the test procedure to ensure that test requirements have been satisfied.

5.8 The WCS manager shall review the testing results and if acceptable, forward the test procedure and test results to the WCS records center in accordance with QA-17.1 "QA Records".

5.9 If the WCS manager determines that the test results are not acceptable:

5.9.1 Repeat the test and evaluate the results; or

5.9.2 Nonconform the results in accordance with WCS procedure QA-16.1, "Corrective Action" and reject the item for use; or

5.9.3 Have test results evaluated of use-as-is.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

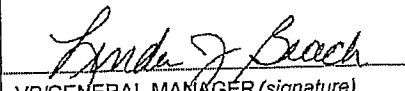
6.2.1 Testing Procedures

6.2.2 Testing Results/Records

7.0 REFERENCES

WCS QA Plan

CONTROL OF MEASURING AND TESTING EQUIPMENT

PROCEDURE APPROVALS:		
Pete Rodriguez		2-1-10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach		2/1/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

The purpose of this procedure is to define the methods and responsibilities for ensuring those tools, gages, instruments, and other measuring and test equipment used for quality affecting activities are controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits. Calibration and control shall not be required for rulers, tape measures, levels and other normal commercial equipment that provides adequate accuracy.

2.0 DEFINITIONS

Responsible Manager - The manager of the department or project assigned primary responsibility for use of the subject measuring and testing equipment (M&TE).

3.0 RESPONSIBILITIES

3.1 The **Responsible Manager** is responsible for ensuring that M&TE used within their functional area of responsibility is:

3.1.1 Procured from suppliers identified on the Waste Control Specialists LLC (WCS) Qualified Supplier List according to the procurement document requirements of QA-4.1, "Procurement Document Control".

3.1.2 Properly maintained, tracked, calibrated, identified, and controlled in accordance with this procedure and any pertinent equipment-specific procedures and instructions.

3.2 All **WCS employees** are responsible for ensuring that M&TE has been pre-calibrated prior to use and is acceptable for use as specified in the pertinent procedure and instruction.

3.3 The **Quality Assurance Manager** is responsible for performing Quality Assurance (QA) Audits to verify the adequacy and implementation of M&TE procedures and instructions.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 Prerequisites

The Responsible Manager shall ensure that suppliers contracted to calibrate quality affecting M&TE are on the WCS Qualified Suppliers List.

4.2 Precautions and Limitations

None.

5.0 INSTRUCTIONS

5.1 WCS managers shall prepare calibration procedures or instructions for each M&TE type used within their functional area of responsibility. The procedure or instruction shall address the following as applicable to the M&TE being calibrated:

5.1.1 Measuring and test equipment (M&TE) shall be calibrated, adjusted and maintained at prescribed intervals or, prior to use, against reference calibration standards having traceability to nationally recognized standards. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented on the calibration documentation.

5.1.2 Calibration standards shall have a greater accuracy than the required accuracy of the M&TE being calibrated. If calibration standards with a greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used, provided they are shown to meet the pertinent requirements.

5.1.3 The basis for the calibration acceptance shall be documented.

5.1.4 The method and interval of calibration for each device shall be defined and specified based on the type of equipment, stability characteristics, required accuracy, intended use and other conditions affecting measurement control.

5.1.5 Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration and uniquely identified to provide traceability to its calibration data.

5.1.6 Controls and instructions for proper handling and storage.

5.1.7 The Responsible Manager shall maintain, and make available for QA review, an M&TE inventory tracking list of the M&TE used within their functional area of responsibility. At a minimum the M&TE inventory tracking list shall include or reference the:

- Equipment manufacturer,
- Name or description including, model number, and serial number or unique number,
- Supplier of calibration service,
- Calibration procedure or instruction number, if applicable,
- Calibration interval, and unless the M&TE must be calibrated daily to be used (i.e., analytical laboratory instrument), the:
  - Date of last calibration, and
  - Calibration expiration (recalibration due) date.

5.1.8 The Responsible Manager shall ensure that calibration records, including calibration logbooks and certificates of calibration providing for traceability to a nationally recognized calibration standard used for calibration (if applicable), are managed according to WCS Procedure QA-17.1, "Quality Assurance Records".

5.1.9 WCS manager shall ensure that when M&TE is found out-of-calibration, the validity of any results obtained using that equipment since its last valid calibration are evaluated to verify the acceptability of previously collected data, processes monitored, or items previously inspected or tested. If any M&TE is consistently found to be out-of-calibration during periodic testing or the recalibration process, it shall be repaired or replaced.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records;" and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.2.1 Calibration instructions or procedures

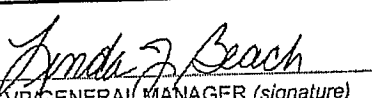
6.2.2 M&TE Inventory

6.2.3 M&TE Calibration Records

7.0 REFERENCES

WCS QA Plan

CORRECTIVE ACTION MANAGEMENT

PROCEDURE APPROVALS:		
Pete Rodriguez		1/27/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach		2/3/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

This procedure describes the Waste Control Specialists LLC (WCS) corrective action process. Action/Issue Management System (AIMS) is the system that WCS uses to implement the corrective action process. AIMS includes the identification, screening, notification, evaluation/resolution, verification and ultimate closure of the issue. This procedure also documents the disposition of nonconforming items and opportunities for improvement.

2.0 DEFINITIONS

2.1 AIMS – Action and Issue Management System, The process used to document an issue and track the issue until the issue has been resolved and closed.

2.2 Guidance - A suggested practice that is not mandatory in this procedure but is intended to comply with good management practices. The word *should* denotes guidance; the word *shall* denotes a requirement.

2.3 Deficiency (DEF) - Failure to meet a regulatory or management requirement (e.g., policy, procedure). Deficiency also includes events, which is an incident or accident occurring at the site that adversely affects the radiological and/or industrial health and safety of employees. Deficiencies require a corrective action plan and for deficiencies categorized as significant, a root cause may be required.

2.4 Opportunity for Improvement (OFI) - Recommendations, observations, employee improvement ideas, safety suggestions and process improvement ideas submitted to AIMS by employees or external sources such as audits or assessments. An OFI that is accepted by WCS management requires an action plan to address OFI and does not require documented completion verification for closure.

2.5 Directed Action (DA) - Assignments or actions that are not deficiencies or opportunities for improvement but WCS management wants the assignments or actions managed and tracked to closure.

2.6 Nonconforming Item - Items that do not conform to specified requirements. Item, for purposes of this procedure, is an all inclusive term meaning: a structure, system, subsystem, component, equipment, part or material.

2.7 Screening and Categorization - The process of assigning defined coding to each issue, such as significance, priority, trend code, type, issue owner and trending of the facility performance.

2.8 Lessons Learned - A communication of best practices or weakness identified during issue processing that is passed on to the employees impacted by the event so as to improve the work process or items and prevent recurrence.

2.9 Design Authority - The organization having the responsibility and authority for approving the design basis, the configuration and subsequent changes to the approved design.

2.10 Corrective Action Plan - The documented evaluation of a deficiency and the corrective action steps to correct the issue, including action steps to prevent recurrence of the issue.

2.11 Action Plan - The documented evaluation of an OFI and the action plan needed to address the OFI.

3.0 RESPONSIBILITIES

3.1 WCS employees are responsible for:

3.1.1 Initiating AIMS items when they observe issues that require corrective or preventive actions.

3.1.2 Taking immediate actions to mitigate any unsafe work condition.

3.1.3 Stopping work and reporting a condition that is unsafe or could result in an unsafe condition or produce an unsatisfactory quality condition or product.

3.2 The **WCS Directors, Managers and Supervisors** are responsible for:

3.2.1 Participating on screening and categorization teams as directed by the WCS Vice President/General Manager (VP/GM).

3.2.2 Encouraging WCS employees to use AIMS to identify DEFs and OFIs.

3.2.3 Evaluating AIMS items and preparing corrective action plans.

3.2.4 Completing the specified corrective actions.

3.2.5 Notifying the VP/GM when all corrective actions needed to close an issue have been completed.

3.2.6 Notifying the VP/GM of resolution and recommendation for closure of OFIs, based on an appropriate justification and when no further action is necessary and/or practical.

3.3 The **Vice President/General Manager (VP/GM)** is responsible for:

3.3.1 Ensuring appropriate screening and categorizing of AIMS issues.

3.3.2 Approving AIMS evaluations and corrective action plans.

3.3.3 Approving AIMS evaluation and justification for resolution and closure recommendations of OFIs.

3.3.4 Assigning root cause investigation teams when applicable.

3.3.5 Verifying closure of AIMS items.

3.4 The **WCS QA Manager** is responsible for:

3.4.1 Participating on the screening and categorization team.

3.4.2 Maintaining the status of the AIMS items.

3.4.3 Providing status reports to the WCS management team.

3.4.4 Approving AIMS evaluations and corrective action plans.

3.4.5 Verifying and confirming the closure of AIMS items.

3.4.6 Periodic trending of AIMS items.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 Prerequisites

4.1.1 The screening and categorization teams should be trained in the guidance documents needed to successfully screen issues. The guidance documents include Appendices A and B of this procedure.

4.2 Precautions and Limitations

4.2.1 Timely corrective action planning and correcting issues is necessary to ensure that a successful issue management system is effective.

4.2.2 AIMS is not limited to quality issues. WCS employees are encouraged to identify suggestions that improve safety and compliance, reduce environmental impacts, and increase the efficiency and effectiveness of the WCS work procedures and practices.

4.2.3 Actions plan should not be confused with "Corrective Action Plans" (CAP). CAPs are required for Deficiencies. Action Plans are used to address OFIs. An action plan is required if the OFI is accepted for processing and will contain the proposed resolution and justification for closure of the issue.

5.0 INSTRUCTIONS

This section is divided into six major sections that define the process steps for Issue Identification, Issue Screening and Categorization, Issue Evaluation and Action Plan Development, Action Completion, Issue Closure and Issue Tracking, Status Reporting and Trending.

5.1 Issue Identification

WCS employees are responsible for stopping work when a significant issue adverse to quality, safety or work conditions could result in an immediate hazard to working personnel, the public or the environment.

5.1.1 All WCS employees have an obligation to promptly identify and report issues which have an adverse impact on quality, safety and regulatory compliance. WCS employees' first obligation is to promptly report issues to their manager. Initial reporting can be verbal or in writing. If the issue is minor and can be immediately corrected, the issue should be promptly corrected.

5.1.1.1 Employees should document their issue on FORM QA 16.1-1, "AIMS Issue Report". If you would like to be contacted by the person assigned to evaluate your issue, please mark the applicable block on the form.

5.1.1.2 AIMS issues can be documented by using an email and sent to AIMS@wcstexas.com, dropped off at the AIMS coordinator, the WCS Receptionist desk during normal office hours, or submitted directly to the VP/GM.

5.1.2 Employees that identify issues shall provide as much information as is known on the issue report. Providing information will help the person who evaluates the issue and writes the action plan.

5.1.3 Employees are encouraged to submit ideas and suggestions for improving their work environments and work processes. Employee ideas and suggestions for improving their work environments and work processes will be evaluated by the VP/GM.

5.1.4 Issues resulting from external sources such as regulators and customer audits and surveillances shall be initiated by the responsible WCS Director for AIMS evaluation. Since these issues have already been documented on respective external source documents, form QA 16.1-2, "AIMS Corrective Action Report" should be used to document the issue into AIMS for screening, categorization and processing.

5.2 Issue Screening and Categorization

5.2.1 The WCS VP/GM should establish as appropriate an issue screening and categorization team.

5.2.1.1 The WCS VP/GM will establish a charter to document the methods used by the Screening and Categorization Team (SCT) in completing their assigned responsibilities as defined in this procedure. This charter also outlines the responsibilities of each responsible organization in processing AIMS evaluation, corrective action plans and closure.

5.2.1.2 The team will meet as directed by the VP/GM.

5.2.2 The screening and categorization team should use the guidance provided in Appendix A "Guidance for the Application of Priority, Timeliness and Significance" for screening and categorization of each identified issue. Appendix B "Suggested Format for Collecting and Documenting Screening and Categorization Data" provides a suggested format for collecting the screening and categorization data.

5.2.3 In cases where multiple issues are identified on a single AIMS report, the team should evaluate if the AIMS report should be divided into multiple AIMS reports to facilitate more efficient corrective action plan development and closure.

5.2.4 If the screening and categorization team determines that the issue meets the definition of a nonconforming item, an assignment shall be made to immediately identify, tag if practical and segregate the item to ensure that the item is not used or installed until the item has been evaluated and dispositioned.

5.2.5 If the screening and categorization team determines that an issue is a violation of local, state, or federal regulation, prompt notification to the WCS' Executive Vice President of Licensing and the Facility Compliance Manager is required.

5.2.6 If the screening and categorization team determines that an issue is not valid, the VP/GM shall assign the appropriate team member the task to contact the originator and provide the reason for not processing the issue.

5.2.7 The WCS QA Manager or designee shall document the data collected as a result of the screening and update the AIMS data files. Appendix B provides a suggested format for collecting the screening and categorization data.

5.2.8 Upon completion of the issue screening and categorization, the responsible director/manager shall be notified to evaluate the issue and develop the corrective action plan. Form QA-16.1-2 shall be used by the assigned responsible Director/Manager to document the evaluation and the corrective action plan. In the case of an OFI that does not require a corrective action plan, an appropriate action plan with proposed resolution and justification for closure may also be documented on form QA-16.1-2.

5.3 Issue Evaluation and Action Plan Development

Form QA-16.1-2 "Aims Corrective Action Report" shall be used to document the evaluation and the respective corrective action plan for deficiencies.

5.3.1 Priority 1 issues must be evaluated by root cause investigation as specified in Appendix A. The responsible Director/Manager shall evaluate the assigned AIMS report and develop a corrective action plan to correct the issue and prevent recurrence. The evaluation and the corrective action plan should address the following:

5.3.1.1 Contacting the individual that identified the issue to ensure that full understanding of the issue is being evaluated.

5.3.1.2 Immediate corrective actions to temporarily control the issue and reduce hazardous conditions.

5.3.1.3 Perform an extent of conditions review to determine the full and generic implications of the issue. If it is determined that the issue is not an isolated issue and exists in other WCS areas or organizations include corrective actions to prevent recurrence.

5.3.1.4 Assigning individuals for each corrective action.

5.3.1.5 Assigning realistic completion dates to each corrective action.

5.3.2 If the issue is a nonconforming item, the following evaluation criteria shall be used and dispositioned into one of the following categories:

5.3.2.1 Reject/Scrap - The item cannot be brought back into compliance with requirements.

5.3.2.2 Rework - Additional work, either completion or correction, will bring a nonconforming item into compliance with the original specified requirements. The corrective action plan shall contain a requirement to reexamine (inspection or test) the item to verify acceptability.

5.3.2.3 Use As Is – The evaluation for use as is must determine if the item is suitable without rework or repair for the item's intended use, and its reliability

and performance will not be affected even though the item does not conform to the specified requirements. The category "Use As Is" requires a technical justification. This justification must be completed by the design authority that specified the original requirement. Exceptions to the technical justification shall be documented and approved by the VP/GM. The technical justification shall be included with the AIMS Corrective Action Report.

5.3.2.4 Repair - Item can be returned to an acceptable condition but not according to the original specified requirements. The corrective action plan of the item to be repaired shall contain a requirement to reexamine (inspection or test) the item to verify acceptability. The category "Repair" requires a technical justification. This justification must be completed by the design authority that specified the original requirement. Exceptions to the technical justification shall be documented and approved by the VP/GM. The technical justification shall be included with the AIMS Corrective Action Report.

5.3.3 The AIMS Coordinator will specify the evaluation and corrective action plan due dates when issuing AIMS to the Responsible/Director/Manager.

5.3.4 The responsible Director/Manager shall confirm the priority assigned to the AIMS item and prepare the evaluation and corrective action plan on the schedule provided in the Appendix A. If the schedule cannot be met, contact the VP/GM. Also notify the Manager of Facility Compliance if a corrective action associated with a regulatory commitment, such as an enforcement action, is not met, cannot be met, or needs to be revised. If a new date is established the VP/GM will contact the QA Manager to update the date in the AIMS data file.

5.4 Action Completion

Form QA-16.1-2 "AIMS Corrective Action Report" shall be used to document the completion of the assigned corrective actions.

5.4.1 The individuals assigned to perform the corrective action shall confirm that the actions assigned are achievable by the schedule dates provided. If the schedule is not realistic, contact the responsible Director/Manager.

5.4.2 If the approved Corrective Action Plan (CAP) actions require an extension of time to complete, the Director/Manager shall request an extension of time.

5.4.2.1 The requested extension can be a face to face meeting with the VP/GM or a documented email.

5.4.2.2 In either case, the approved extension request shall be provided to the QA Manager or designee so that the AIMS data file can be amended.

5.4.3 The individuals assigned to complete the actions should complete the actions and notify the responsible Director/Manager when the actions have been completed.

5.4.4 The responsible Director/Manager shall verify that all actions have been completed as specified on the corrective action plan. If conditions have not been corrected or have not been performed as specified, contact the individuals assigned the actions to redo the action; or mutually agree on a more effective course of action.

5.4.5 When all actions have been completed on the assigned AIMS, the responsible Director/Manager shall provide objective evidence to the QA Manager and the VP/GM for a closure review.

5.5 Issue Closure

Form QA-16.1-2 "AIMS Corrective Action Report" shall be used to document the closure.

5.5.1 When all specified actions have been completed on an AIMS item, the responsible Director/Manager shall assemble the supporting objective evidence (i.e., training record, procedure revision) and submit the collected data and/or resolution and justification statement to the QA Manager and the VP/GM for a closure review.

5.5.2 The VP/GM shall review the closure data and if acceptable, approve closure and submit to the QA Manager for updating the AIMS data files.

5.5.3 The WCS QA Manager shall review the approve closure data.

5.5.4 The WCS QA Manager or designee shall update the respective AIMS data files, indicating closure.

5.5.5 The WCS QA Manager or designee shall submit the closure documents to the records management system in accordance with records management requirements.

- The closure documents should be scanned and transmitted to the records system.

5.6 Issue Tracking, Status Reporting and Trending

5.6.1 The WCS QA Manager or designee is responsible for tracking the status of AIMS item from initiation to closure. The status information shall be retained in an electronic data file.

5.6.2 The WCS responsible Directors/Managers should promptly notify the WCS QA Manager if errors are detected and if a new change in status has occurred. This is especially important for completion of individual assigned corrective actions.

5.6.3 The WCS QA Manager will make the current status of AIMS item available on a WCS facility drive. WCS Directors/Managers should access this file for the most current status.

5.6.4 The WCS QA Manager shall utilize the AIMS data files to trend the data and review for potential adverse trends. If adverse trends are identified, the trend shall be documented in AIMS for evaluation and corrective actions.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records and are to be retained for the life of the facility:

6.2.1 Form QA-16.1-1, "AIMS Issue Report"

6.2.2 Form QA-16.1-2, "AIMS Corrective Action Report" (Quality Levels 1 & 2)

7.0 REFERENCES

7.1 QA-16.2 "Stop Work"

AIMS Issue Report
QA-16.1-1
EXAMPLE

AIMS ISSUE REPORT	**Form QA-16.1-1**

An issue can be a deficiency, safety concern, recommendation or an employee improvement idea. Please provide as much information as possible. It will be helpful in evaluating this issue. This form can be sent by email to AIMS@wcstexas.com, it can be dropped off at the WCS receptionist's desk, it can be dropped off at the General Manager's office or left anonymously in the General Managers interoffice mail box.

AIMS DESCRIPTION:

ORIGINATOR NAME OR ☐ NA: ANONYMOUS	DATE SUBMITTED	Do you want to be contacted when your issue is being evaluated and closed?
		◊ Yes ◊ No

Note: An AIMS may also be submitted directly by sending the issue description to AIMS@wcstexas.com. The AIMS Coordinator will place the issue on the proper forms for processing.

AIMS Corrective Action Report
QA-16.1-2
EXAMPLE

AIMS CORRECTIVE ACTION REPORT		Form QA-16.1-2
Identified By:	Evaluation Assigned to:	AIMS Number and Issue Type

ISSUE DESCRIPTION:

EVALUATION::

#	CORRECTIVE ACTION PLAN:	ACTION ASSIGNEE	DUE DATE	DATE COMPLETED

Evaluation and CAP Approvals:
Responsible Manager/Date_____
General Manager/Date _____
QA Manager/Date (Deficiencies Only)_____
Radiation Safety Officer/Date (all Rad Issues)

Closure Approvals:
Responsible Manager/Date_____
General Manager/Date _____
QA Manager/Date _____
Radiation Safety Officer/Date (all Rad Issues)_____

APPENDIX A (page 1 of 2)

Guidance for Application of Priority, Timeliness and Significance

Deficiency

	Priority 1 Regulation Significant			Priority 2 Management Significant			Priority 3 Minor Non Quality		
	Quality Level	Approval		Quality Level	Approval		Quality Level	Approval	
Process Step	1 or 2	QA	VP/GM	1 or 2	QA	VP/GM	3	QA	GM
Root Cause Required	Y	Y	Y	N/R#	N/A	N/R#	N/A	N/A	N/A
Prepare Corrective Action Plan (CAP)	14 days*	N/A	N.A	21 Days	N/A	N/A	21 Days	N/A	N/A
Review & Approve CAP	14 days	Y	Y	14 Days	Y	Y	14 Days	N/A	Y
Complete Specified Actions	As per CAP	N/A	N/A	As per CAP	N/A	N/A	As per CAP	N/A	N/A
Closeout Review after CAP completed	14 days	Y	Y	14 Days	Y	Y	14 Days	N/A	Y

Note: * Exception applies when a root cause is required as follows- 14 days after root cause report approved. All days are calendar days.
N/R #- Not required but the VP/GM can direct a root cause be performed.

Opportunities for Improvement (OFI)

Process Step	N/A
Evaluate- Accept or Reject OFI	21 Days
If accepted, prepare Action Plan (AP); If not accepted, document and notify the person that initiated the OFI.	21 Days
Review and Approve AP	14 Days
Complete Specified Actions	As per the Action Plan
Closeout Review after AP completed	14 Days

Note: OFIs do not require QA approval or Closeout Review. The VP/GM has responsibility for AP approval and closeout

Appendix A (page 2 of 2)

Guidance for the Application of Priority and Significance		
Issue Category	**Priority**	**Basic Criteria Description**
Deficiency	1	Regulation Significant Failure to meet a facility performance objective- such as protection of the health and safety of the worker, the public or the environment. When WCS exceeds a regulatory limit as stated in their license or permit, this category will apply. Significant safety and quality deficiencies also fall into this category.
Deficiency	2	Management Significant Failure to meet a WCS managerial requirement (as defined in procedures and directives) that impacts operating cost or schedule. Trends and recurring deficiencies fall into this category. If the issue has a financial impact of > $50k, this is a significant business impact.
Deficiency	3	Minor Non Q Failure to meet a management requirement (as defined in procedures and directives) that has low impact, no significant consequences and can be readily corrected.
Deficiency	Decline	Deficiency is not valid based on management evaluation. Initiating employee should be called and provided with the reasoning.

Appendix B

Suggested Format for Collecting and Documenting Screening and Categorization Data

AIMS Number:	
◊Yes ◊No	Is this a valid issue? Assign Number If No, briefly explain.
◊Yes ◊No	Does this issue warrant a Stop Work? If Yes, Follow QA-16.2
◊Yes ◊No	Does this issue require a corporate notification? If yes, notify corporate.
◊Yes ◊No	Does this issue require notification to a regulator? If yes, contact compliance
◊Yes ◊No	Does this issue require notification to a customer? If yes, Contact Business Development:
◊Yes ◊No	Does a lesson learned communication need to be prepared? If yes, assign to:
◊Yes ◊No	Does this issue meet the definition for a nonconforming item? If yes immediately tag and segregate the item, if possible.
◊Yes ◊No	Is the issue related to Radiation Safety? If yes, immediately notify the Radiation Safety Officer.
◊Yes ◊No	Is the issue potentially facility wide? If yes, conduct and extent of condition review.
◊Yes ◊No	Is the issue related to a noncompliance? If yes, immediately notify the Manager of Facility Compliance, and Senior Vice President of Licensing and Regulatory Affairs.

Refer to Appendix A for guidance on establishing priority, if needed.

Issue Type: ◊ Deficiency ◊ Opportunity for Improvement ◊ Directed Action ◊ Non-conforming item

Priority Level: ◊ 1 ◊ 2 ◊ 3 Priority applies to Deficiencies only.

Quality Level: ◊ 1 ◊ 2 ◊ 3 Applies to Deficiencies only. Refer to WCS QA Plan for criteria.

Issue Evaluation and Corrective Action Plan assignment to:

Facility: ◊Low Level ◊Byproduct ◊ RCRA Landfill ◊ MWTF ◊ Rail ◊ Lab ◊ CSB ◊STAB ◊BSU ◊BSA-1 ◊ LSA ◊ Admin ◊ Other ◊TBD ◊DD

Issue Identified by: ◊ QA ◊ Worker ◊ Regulator ◊ Customer

Root Cause Required ◊No ◊Yes If yes, assigned to :_____

Apparent Trend Code (Deficiencies Only) :

Issue Subject: ◊ Industrial Safety ◊Radiation Safety ◊ Operations ◊ Admin Services ◊ Licensing & Compliance ◊ QA◊ Environmental ◊ Maintenance ◊ Other ◊ Reserved

WCS Contractor Issue: Specify Contractor Name:

WCS Supplier Issue: Specify Supplier Name:

WCS Procedure Number and Revision, if a procedure violation:

Reserved

Reserved

Reserved

Reserved

Reserved

Reserved

Date Screened: **Date Data file Updated:** **Recorded By:**

STOP WORK

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/1/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda J. Beach	2/4/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

This procedure authorizes and requires all Waste Control Specialists LLC (WCS) employees and on-site contractors to issue a stop work order whenever a significant and immediate threat to human health and safety or the environment is identified or whenever continuance of work will adversely affect quality requirements. This procedure provides instructions for documentation of stop work orders and actions necessary to resume work.

The documentation requirements of this procedure are not intended to be applicable to the everyday type of precautionary delays resulting from pursuance of routine safe work practices.

2.0 DEFINITIONS

Responsible Manager - The manager of the department that is primarily responsible for the deficient work activity (see limitation 4.2.1 below).

3.0 RESPONSIBILITIES

3.1 **All WCS employees and contractors** are responsible for:

3.1.1 Issuing verbal stop work orders when an imminent safety, health or environmental hazard is discovered or when continuance of work would adversely affect quality requirements.

3.1.2 Immediately reporting stop work orders to their supervisor and cognizant WCS management.

3.2 **Responsible Managers** are responsible for:

3.2.1 Promptly evaluating and reporting Stop Work Orders to the VP/General Manager and Quality Assurance Manager; the Health, Safety and Security Director and the Environmental Director, if the matter is related to industrial safety or the environment; and the Radiation Safety Officer, if the matter is related to radiological safety.

3.2.2 Ensuring that Stop Work Orders are properly documented and reviewed by completing form QA-16.2-1, "Stop Work Report" (SWR).

3.3 The **Quality Assurance (QA) Manager** is responsible for determining whether SWR documentation is appropriate for the reported condition, and reviewing/approving SWR initiation and closure information.

3.4 The **VP/General Manager** is responsible for providing oversight for designation of an appropriate team of cognizant managers to address the stop work condition and any related deficiencies, and review/approval of SWR initiation and closure information.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

4.1 Prerequisites

All WCS Facility Personnel shall receive documented training on the requirements of this procedure.

4.2 Precautions and Limitations

4.2.1 In cases of cross-functional responsibilities related to a stop work condition, the QA Manager shall refer the Responsible Manager determination to the next management level with authority over the related cross-functional responsibilities.

4.2.2 Disputes involving differences of opinion regarding quality affecting work between line organizations and QA, shall be progressively escalated starting with the QA Director to the President until the dispute is settled.

5.0 INSTRUCTIONS

5.1 General

5.1.1 All WCS employees and contractors performing work at the facility shall identify and report actual and anticipated work hazards and conditions adverse to quality (CAQ's).

5.1.2 All employees and contractors shall conform to stop work orders.

5.2 Issuance of Verbal Stop Work Orders

If there is an immediate danger to human health or the environment:

5.2.1 Immediately issue a verbal Stop Work Order to workers in the affected work area(s) upon identification of a condition that presents an immediate danger to human health or the environment.

5.2.2 If possible to do so safely, ensure that work equipment and materials are placed in a safe condition.

5.2.3 If necessary to prevent injury, exposure, or contamination, evacuate and/or secure the area as necessary to prevent unauthorized access.

5.2.4 If there is an emergency notify the Emergency Coordinator(s) immediately. Ensure that your supervisor, the Responsible Manager, and appropriate responsible cognizant manager(s) (e.g., HS&S Director, RSO, etc.) are notified immediately.

5.2.5 If there is a need to stop work for mitigation or prevention of a condition adverse to quality; issue a verbal Stop Work Order to personnel as necessary to prevent or mitigate the CAQ, and if time permits - notify and consult with your supervisor and the QA Manager before stopping work. The QA Manager shall notify and consult with cognizant management to determine if the issue of a Stop Work Order is appropriate.

5.3 Stop Work Evaluation

The Responsible Manager or delegate shall:

5.3.1 Promptly form a team, including appropriate responsible cognizant manager(s) (e.g., Health and Safety Manager, RSO, etc.) and evaluate the hazard(s) and/or deficient condition(s) associated with the verbal Stop Work Order. Determine, and begin implementation of, the immediate, remedial, and preventative action(s) necessary to resume work in a manner that ensures hazards and/or deficient conditions are eliminated.

5.3.2 If it is determined that work may be resumed with no or minimal immediate action, then the verbal stop work order may be considered a routine precautionary safe work practice and stop work documentation may not be required. Consult with the QA Manager for assistance in determining if documentation is required.

5.4 Preliminary SWR Tracking

If a SWR is to be completed:

5.4.1 The QA Manager shall promptly provide the Responsible Manager with the next SWR ID number available in the SWR tracking system and may assign "SWR Keywords" to assist in referencing of the SWR.

5.4.2 The QA Manager shall ensure entry of "place-holder" information in the SWR tracking system as necessary to correlate the SWR ID number with the respective deficiency issue. The place-holder information shall include: SWR ID Number; SWR Keywords; Date (SWR) Opened; Initiator Name and Initiation Date/Time; and the Names and Notification Dates/Times for the Responsible Manager, and QA Representative Notified.

5.5 SWR Initiation and Approval

The Responsible Manager or delegate shall:

5.5.1 Obtain a stop work identification number and SWR keywords from QA.

5.5.2 Enter SWR initiation information on QA-16.2-1, "Stop Work Report" as prompted on the report.

5.5.3 Review/edit the recorded information for accuracy and completeness.

5.5.4 Obtain SWR initiation approval signatures.

5.6 Data Entry and Formal Notification of SWR Initiation

5.6.1 Deliver the SWR to the QA Manager. The QA Manager shall complete initiation of the SWR by ensuring that:

5.6.2 The approved initiation information is entered into the tracking system;

5.6.3 Affected personnel are notified by distribution of the initiated SWR;

5.6.4 "Database Login" and "Distributed To" information is completed; and the SWR original is returned to the Responsible Manager.

Note
Initiation of the SWR is now complete.

5.7 SWR Closure and Approval

The Responsible Manager shall:

5.7.1 Monitor the status and facilitate completion of actions required for work resumption.

5.7.2 Obtain QA concurrence for modification to follow-up (start work) actions.

5.7.3 When the required actions have been completed:

a) Specify the follow-up actions taken by checking or placing an "X" in either the "Follow-up Actions Completed as Approved Above" block, or the "Modified Follow-Up Actions Completed with Prior Approval" block.

b) If modified follow-up (start work) actions were implemented, use the "Follow-Up Actions Taken Remarks" section to document the modified actions taken and references to related and/or attached objective evidence documents

c) Ensure the appropriate signatures for approval and concurrence for resumption of work are recorded on the report.

5.7.4 Deliver the SWR to the QA Manager. The QA Manager shall complete closure of the SWR by ensuring that:

a) The approved closure information is entered into the tracking system;

b) Affected personnel are further notified by distribution of the completed SWR;

c) The "Database Logout" and "Distributed To" information is completed; and the SWR original is forwarded to Document/Records Control

Note
Closure of the SWR is now complete.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, Quality Assurance Records; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

Stop Work Report Forms, QA-16.2-1 are quality assurance records.

7.0 REFERENCES

7.1 WCS QA Plan

WASTECONTROL
SPECIALISTS LLC

SWR Stop Work Report

SWR INITIATION AND APPROVAL

SWR #:	SWR KEYWORDS:	INITIATOR (Name)	INITIATION DATE:	INITIATION TIME:
SWR-				

RESPONSIBLE MANAGER NOTIFIED(Name)	RESPONSIBLE MANAGER POSITION:	NOTIFIED BY: (Name)	NOTIFICATION DATE:	NOTIFICATION TIME:

QA RESPRESENTATIVE NOTIFIED(Name)	QA REPRESENTATIVE POSITION:	NOTIFIED BY: (Name)	NOTIFICATION DATE:	NOTIFICATION TIME:

PROBLEM DESCRIPTION:(Condition requiring work stoppage) ☐ Emergency Plan Activated ☐ Nonconforming Item ☐ Deficient Activity

SCOPE OF WORK STOPPAGE: (Project, process, sub-process, task, etc.)

IMMEDIATE ACTION(S) TAKEN:

FOLLOW-UP ACTION(S) TO BE TAKEN BEFORE RESUMPTION OF WORK:

REMARKS: (include reference to any pertinent supplemental NCIR or CAR)

WASTECONTROL
SPECIALISTS LLC

SWR Stop Work Report

SWR #:	SWR KEYWORDS:	RESPONSIBLE MANAGER: (Name)	CLOSURE DUE DATE:
SWR-			

SWR INITIATION APPROVALS: (signatures required before disposition implementation)

Responsible Manager (print name)	Responsible Manager (signature)	Date
General Manager (print name)	General Manager (signature)	Date
Quality Assurance Manager(print name)	Quality Assurance Manager (signature)	Date

Opened SWR To Be Distributed To:					
Db Login Date:		By:	Distribution Date:		By:

SWR CLOSURE AND APPROVAL:

☐ Follow-up Actions Completed as Approved Above.

☐ Modified Follow-up Actions Completed with Prior Approval.(indicate modified follow-up actions completed in remarks below)

FOLLOW-UP ACTIONS TAKEN REMARKS:

SWR CLOSURE APPROVALS: (signatures required before resumption of work)

Responsible Manager (print name)	Responsible Manager (signature)	Date
VP/General Manager (print name)	VP/General Manager (signature)	Date
Quality Assurance Manager (print name)	Quality Assurance Manager (signature)	Date

Closed SWR To Be Distributed To:					
Db Logout Date:		By:	Distribution Date:		By:

QUALITY ASSURANCE RECORDS

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/2/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER *(signature)*	DATE
Linda Beach	Linda J Beach	2/4/10
VP/GENERAL MANAGER *(printed name)*	VP/GENERAL MANAGER *(signature)*	DATE

1.0 PURPOSE AND SCOPE

This procedure defines and establishes a system for the handling, maintenance, and disposition of quality assurance records and provides requirements for the validity and security of quality assurance records produced by Waste Control Specialists LLC (WCS). This procedure is applicable to those records that furnish documentary evidence of the quality of activities, items, materials, and contractual services related to WCS operations.

2.0 DEFINITIONS

2.1 Quality Assurance Record - An authenticated record that provides objective evidence of the quality of items or activities (e.g., records for site characterization, performance assessments, waste characterization, personnel qualification and training/certification, and records that document regulatory compliance).

2.2 Electronic Record - A record in a form that is readable only by a computer or other electronic equipment. Electronic records are most frequently recorded on media such as disk, diskette, tape, and tape cartridges.

2.3 Active Record - A record that is necessary to conduct the current business and is therefore maintained in the work area until it becomes a completed record.

2.4 Completed Record - A record that contains accurate and proper documentation to the extent required to support the organization, functions, policies, decisions, procedures, or essential transactions of WCS.

2.5 Lifetime records are those that meet one or more of the following criteria:

2.5.1 Those which would be of significant value in demonstrating capability for safe operation;

2.5.2 Those which would be of significant value in maintaining, reworking, repairing, replacing or modifying an item;

2.5.3 Those which would be of significant value in determining the cause of an accident or malfunction of an item;

2.5.4 Those, which provide required baseline data for in-service inspections; and/or

2.5.5 Other records as required to satisfy regulatory requirements and business purposes.

2.6 Nonpermanent Records - Those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. QA audits and surveillance reports are examples of nonpermanent records.

2.7 WCS Records Center - A facility, container, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

2.7.1 Natural disasters such as wind, floods or fires;

2.7.2 Environmental conditions such as high and low temperature and humidity; and

2.7.3 Infestation of insects, mold and rodents.

2.8 The WCS Records Center shall meet the requirements as specified in ASME NQA-1, 1994 edition, Section 17, "QA Records", supplement 17S-1 "Supplemental Requirements for QA Records", Section 4.4, "Storage Facilities."

2.9 Authenticated Records - Records that have been reviewed, signed (or initialed), and dated by responsible personnel as approved.

3.0 RESPONSIBILITIES

3.1 **All WCS employees** are responsible for preparing records that document the activities assigned to them. Each individual that creates records should ensure that they are complete, legible, and accurate for the work being performed.

3.2 **WCS personnel and contractors** are responsible for preparing and safeguarding quality assurance records.

3.3 The **QA Manager** is responsible for the overseeing of the Records Management System.

3.4 **Records Administration** is responsible for receipt, storage, retrieval, and archiving of QA records. Records Administration is also responsible for controlling access to the record center.

4.0 PREREQUISITES, PRECAUTIONS, AND LIMITATIONS

None.

5.0 INSTRUCTIONS

5.1 WCS employees shall generate records during the process of implementing the WCS procedures. WCS procedures identify the records and documents required. WCS employees shall protect records in their possession until the record is completed. After a record has been completed, the record shall be submitted to the WCS record center for processing into the records system.

5.2 Records Administration shall:

5.2.1 Review and accept records as valid into the records center if the records are legible, accurate and authenticated;

5.2.2 File the record in accordance with the records indexing system. The indexing system shall include the location of the records within the Records Center and the identification of the item or related activity to which the records pertain;

Note

Records Administration may use an electronic record management system to index records, scan and retrieve records, provided the system has been evaluated and accepted by the WCS QA Manager.

5.2.3 Retrieve records as requested by WCS employees. A sign-out sheet shall be used to identify the records removed from the records center. If practical, copies of requested records can be provided as an option;

5.2.4 Prepare and maintain a listing of responsible individuals who also have uncontrolled access to the QA records. The WCS records specialist shall verify that the designated individuals have been trained in this procedure; and

5.2.5 Disposition nonpermanent records if the following requirements are satisfied:

5.2.5.1 The responsible manager and the QA Manager are in agreement,

5.2.5.2 Regulatory requirements are satisfied,

5.2.5.3 Facility status allows document disposal, and

5.2.5.4 WCS QA requirements are satisfied.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

QA records as defined in section 2.1 above.

7.0 REFERENCES

7.1 WCS QA Plan

AUDITS

PROCEDURE APPROVALS:		
Pete Rodriguez	Pete Rodriguez	2/2/10
QUALITY ASSURANCE MANAGER *(printed name)*	QUALITY ASSURANCE MANAGER (signature)	DATE
Linda Beach	Linda J Beach	2/4/10
VP/GENERAL MANAGER (printed name)	VP/GENERAL MANAGER (signature)	DATE

1.0 PURPOSE AND SCOPE

The purposes of the Waste Control Specialists LLC (WCS) audit program are to:

1.1 Provide verification that specified requirements and performance criteria are met.

1.2 Determine the adequacy, implementation, and effectiveness status of quality-affecting program elements.

1.3 Identify deficiencies, conditions adverse to quality, and opportunities for improvement so they can be evaluated and addressed in a timely manner.

This procedure establishes requirements for auditor qualification and audit: scheduling, preparation, performance, reporting, response, follow-up action, and records. These requirements are based on ASME NQA-1, Requirements 2 and 18. They are applicable to audits performed by WCS personnel and WCS contracted auditors performing: internal quality assurance audits; and supplier qualification audits (when a direct evaluation is made at supplier facilities per NQA-1, Req. 7 (200-C) and QA-7.1, "Supplier Qualification").

2.0 DEFINITIONS

None.

3.0 RESPONSIBILITIES

3.1 **All WCS employees** are responsible for:

3.1.1 Providing auditors with access to work areas and QA records;

3.1.2 Providing information pursuant to identification and correction of conditions adverse to quality; and

3.1.3 Providing service as auditors as directed by their manager and approved by the QA Manager.

3.2 **Responsible Managers** of audited functions are responsible for:

3.2.1 Determining and notifying QA of Supplier/Contractor activities that should be directly audited at the Supplier/Contractor facility;

3.2.2 Attending audit meetings;

3.2.3 Cooperating with auditors pursuant to common interest of identification and correction of conditions adverse to quality;

3.2.4 Identifying known and suspected deficiencies to auditors; and

3.2.5 Providing audit response and corrective action in a timely manner.

3.3 The **Quality Assurance Manager** or delegate is responsible for ensuring implementation of this procedure, including auditor qualification and audit: scheduling, preparation, performance, reporting, response evaluation, and follow-up auditor actions (tracking to closure, etc.).

4.0 PREREQUISITES, PRECAUTIONS AND LIMITATIONS

4.1 Prerequisites

None.

4.2 Precautions and Limitations

None.

5.0 INSTRUCTIONS

5.1 General

5.1.1 Audits shall be performed under the direction and with the approval of the QA Director or QA Manager.

5.1.2 Lead Auditor certification shall be authorized by the QA Director or QA Manager.

5.2 Audit Scheduling

5.2.1 Audit elements to be audited shall be selected based on importance to safety and compliance, previous audit coverage, and deficiency history.

5.2.2 Elements of the following functional areas should be audited in each calendar year or as otherwise specified. Sections 5.2.6 and 5.3.2 apply to functional area audits.

5.2.2.1 Facility Performance Objectives 30 TAC 336.709

This audit scope includes review of WCS processes that ensure or validate the following:

1. Protection of the general population from releases of radioactivity;
2. Protection of individuals from inadvertent intrusion;

3. Protection of individuals during operations; and
4. Stability of the disposal site after closure.

If inspection, surveillance, assessment, or monitoring is used to validate an objective, the QA audit process will validate the result.

5.2.2.2 WCS Radiological Protection Program

The Radiation Protection Program will be audited focusing on compliance with the Radiation Safety Program and pertinent regulations. Audits will be directed by the WCS QA department with the concurrence of the Radiation Safety Committee. Audit schedules for individual activities will be identified with consideration given to the ALARA, regulatory, and safety impact. Topics may be drawn from the Table of Contents of LL-RSP-100 and subordinate implementing procedures.

5.2.2.3 Industrial Health and Safety Program

The Industrial Health and Safety Program will be audited focusing on compliance with the Health and Safety Plan, LL-HS-100, and the Respiratory Protection Program. Audits will be conducted by the WCS QA department with the concurrence of the Health, Safety and Security Director.

5.2.2.4 Environmental Management Program

Environmental Management will be audited focusing on topics that may include compliance with: discharge permits; radiological and non-radiological environmental monitoring programs; Stormwater Pollution and Prevention Program and observations made during the past year. Audits will be scheduled by the WCS QA department with the concurrence of the Environmental Director. Audit schedules for individual activities will be identified with consideration given to the ALARA, regulatory, and safety impact.

5.2.2.5 Operations Programs

Operations will be audited focusing on topics that may include compliance with radioactive material licenses, permits and implementing procedures. Audits will be scheduled with the concurrence of operations management. Audit schedules for individual activities will be identified with consideration given to the ALARA, regulatory, and safety impact.

5.2.2.6 Materials, Parts, and Components

This audit verifies that the line organization and contractor are identifying, controlling, and storing items in accordance with specifications.

5.2.3 Each audited element shall be audited against pertinent: License and Permit commitments; and Regulatory, Quality Assurance, and internal procedure requirements.

5.2.4 Contractor, regulator, and customer audits, inspections, and surveillances may be used to demonstrate coverage if documentation demonstrates applicability and conformance verification.

5.2.5 Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities.

5.2.6 Scheduled audits shall be supplemented by additional audits or surveillance of specific activities when necessary to provide adequate audit coverage.

5.3 Auditor Qualification

5.3.1 Prior to participation in audits or annually, auditors shall:

5.3.1.1 Complete training or required reading on this procedure; and

5.3.1.2 Have, or be given, audit orientation training and have competence in specific audit element requirements. Competence in specific audit element requirements may be achieved by previous education, training, and/or experience, or by completing training on the pertinent requirements prior to participation in audits.

5.3.2 Technical specialists may be used to assess the technical adequacy of technical process provided that the lead auditor verifies that the technical specialist has appropriate qualifications.

5.4 Lead Auditor Qualification

An individual shall meet the following requirements prior to audit participation as a Lead Auditor:

5.4.1 Have obtained his employer's written certification that the individual is capable of communicating effectively, both in writing and orally;

5.4.2 Possess knowledge and understanding of pertinent quality, technical, and regulatory requirements, codes, standards, guides, etc. including those of the WCS QA program;

5.4.3 Be competent in:

5.4.3.1 Auditing techniques of examining, questioning, evaluating, and reporting;

5.4.3.2 Methods of identifying and following up on corrective action items, and closing out audit findings; and

5.4.3.3 Planning audits of quality-affecting activities.

5.4.4 Participate and receive on-the-job training in at least five (5) QA audits, to include at least one (1) nuclear QA audit, within three (3) years prior to qualification.

5.4.5 Pass an oral, written, or practical examination(s) demonstrating competence and ability to apply the body of knowledge above.

5.4.6 Maintain proficiency by one or more of the following annually:

5.4.6.1 Audit participation;

5.4.6.2 Review of the QA program, standards, procedures, and/or other requirements documents;

5.4.6.3 Auditor refresher training; and

5.4.6.4 Lead Auditors that fail to maintain proficiency for a period of two (2) years or more shall not participate in audits as a lead auditor until they are re-qualified according to the original qualification requirements above.

5.4.7 Lead Auditor Qualification shall be certified in writing and include the following information:

5.4.7.1 Employer name;

5.4.7.2 Name of person being certified;

5.4.7.3 Activities certified to perform;

5.4.7.4 The basis of the initial and continuing qualification (education, experience, training, test and/or practical exam results, etc.);

5.4.7.5 Signature of employer's authorized representative; and

5.4.7.6 Date of certification or recertification and certification expiration.

5.5 Audit Preparation

5.5.1 An audit plan shall be developed and documented for each audit. Audit plans shall identify the:

5.5.1.1 Audit scope;

5.5.1.2 Audit personnel, including the Lead Auditor;

5.5.1.3 Activities to be audited;

5.5.1.4 Audit schedule;

5.5.1.5 Personnel to be notified;

5.5.1.6 Audit procedures or checklist;

5.5.1.7 Documents to be reviewed; and

5.5.1.8 Any pertinent audit administration requirements

5.5.2 The audit plan should be routed to pertinent organizations or personnel no later than five business days before audit performance.

5.5.3 Audit checklist items and/or annotated procedures shall include or reference individual requirements and/or lines of inquiry to be used in performance of the audit.

5.5.4 Personnel selected for the audit team should have a level of experience, education, or training commensurate with the scope, complexity, or special nature of the activities they will be auditing.

5.5.5 To ensure that audit personnel have sufficient and organizational freedom to make audits meaningful and successful, audit personnel shall not have direct responsibility for performing the activities they are auditing.

5.6 Audit Performance

5.6.1 A pre-audit conference shall be conducted with the management of the organization to be audited. The purposes of the conference are:

5.6.1.1 Clarifying the audit scope;

5.6.1.2 Meeting counterparts and establishing channels of communication;

5.6.1.3 Confirming audit schedule, discussing the sequence and duration of the audit, and establishing an agreed-to audit agenda;

5.6.1.4 Setting the date and times for the post-audit conference and any intermediate meetings; and

5.6.1.5 Identifying pertinent document locations and sources

5.6.2 Auditors shall have access to appropriate management levels, workers, and work locations within the audited organization as necessary to make audits meaningful and successful.

5.6.3 Activities audited shall be evaluated against specified audit checklist items.

5.6.4 Auditor concerns or discovery of deficiencies may provoke expansion of the audit scope beyond the specified checklist items.

5.6.5 Identified conditions that adversely affect safety or should provoke prompt corrective action shall be immediately reported to the audited organization and affected personnel.

5.6.6 Auditors should use the following auditing methods as pertinent and appropriate:

5.6.6.1 Review of procedures, instructions, or drawings for completeness and adequacy;

5.6.6.2 Inspection of work areas for evidence of implementation and affected personnel to discuss adequacy, implementation, and effectiveness of pertinent program elements;

5.6.6.3 Comparison of personnel training and qualification records with specified training requirements;

5.6.6.4 Observation of accepted items or work and comparison of observations to acceptance criteria or other specified requirements; and

5.6.6.5 Examination of process controls and records to determine conformance to specified requirements.

5.6.7 Objective evidence shall be examined to the depth necessary to determine if the selected program elements are being effectively implemented.

5.6.8 Each Auditor's observations and concerns shall be recorded in auditor notes and reported to the Lead Auditor.

5.6.9 A preliminary classification of audit concerns into findings, observations, and recommendations shall be made prior to the post-audit conference.

5.6.10 A post-audit conference shall be held by the audit team with the management of the audited organization in order to present audit results and clarify any misunderstandings.

5.7 Audit Reporting

5.7.1 Audit Reports shall:

5.7.1.1 Be authenticated with the dated signature of the Lead Auditor;

5.7.1.2 Be issued to the responsible management of the audited organization and the auditors within thirty (30) days of audit conclusion;

5.7.1.3 Describe the final audit scope;

5.7.1.4 Identify the auditors and persons contacted;

5.7.1.5 Identify reviewed documentation;

5.7.1.6 Summarize the audit results, including a statement on the effectiveness of the elements audited; and

5.7.1.7 Classify each audit concern as a finding/deficiency or observation based on the criteria defined below:

a. Findings represent deficiencies that:

- Present an imminent threat to human or environmental health or safety;
- Are deviations from regulatory requirements (including license, permit, and other regulatory authorization commitments) contract provisions, industry standards, internal site procedures

and/or otherwise agreed-upon commitments with regulatory authorities, customers, suppliers, and contractors.

b. Observations represent:

- Conditions adverse to quality that do not meet the criteria for a finding;
- Deviations from management directives, specified policies or best management practices.

5.7.1.8 For each audit finding/deficiency or observation provide:

- An audit report-specific tracking number;
- A one sentence statement describing the finding or observation issue with respect to the pertinent requirement or condition;
- A summary discussion of each audit finding and observation as necessary to clarify the finding or observation issue statement; and
- Recommendations (suggestions intended to assist responsible management in determining corrective actions) as appropriate.

5.8 Audit Response

5.8.1 Functionally responsible management shall promptly:

5.8.1.1 Issue a Stop Work Order according to QA-16.2, Stop Work, whenever a significant and immediate threat to human health is identified or when ever continuance of work will adversely affect quality requirements;

5.8.1.2 Complete any immediate corrective actions necessary to eliminate identified conditions that adversely affect safety or should otherwise provoke prompt corrective action; and

5.8.1.3 Initiate interim measures and notifications as necessary to prevent recurrence of reported deficiencies.

5.8.2 Management that is functionally responsible for each identified deficient activity or nonconforming item shall, within 30 days of audit report issue:

5.8.2.1 Provide the WCS QA Manager with a written response discussing the pertinent finding or observation;

5.8.2.2 Complete initiation of a Corrective Action Report (CAR) according to QA-16.1, "Corrective Action" for identified deficient work activities; and

5.8.2.3 Complete initiation of a CAR according to QA-16.1, "Corrective Action", for identified nonconforming items.

5.8.3 The WCS Quality Assurance Manager or Lead Auditor shall:

5.8.3.1 Evaluate Audit Responses and Initiated CARs and/or NCIRs for adequacy;

5.8.3.2 Recommend CAR/NCIR adequacy improvements to responsible management; and

5.8.3.3 Bring unresolved adequacy issues to the attention of the WCS General Manager and/or corporate management for final resolution.

5.9 Follow-Up Action

5.9.1 Corrective and Disposition actions shall be tracked to completion and verified according to QA-16.1, "Corrective Action".

5.9.2 Upon completion of all corrective and disposition actions resulting from the audit, WCS Quality Assurance shall issue a written closure notification to management of the audited organization and other pertinent functionally responsible management.

6.0 RECORDS

6.1 Records demonstrating performance of this procedure shall be created and retained in accordance with all:

6.1.1 Applicable statutory and regulatory requirements;

6.1.2 WCS procedure QA-17.1, "Quality Assurance Records"; and

6.1.3 Supplemental WCS records management policies and procedures.

6.2 The following completed and authenticated documents are official WCS records:

6.2.1 Auditor Certifications

6.2.2 Audit Plans

6.2.3 Audit Reports

6.2.4 Audit Responses

7.0 REFERENCES

7.1 ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications"

7.2 WCS Procedure QA-7.1, "Supplier Qualification"

7.3 WCS Procedure QA-16.1, "Corrective Action"

7.4 QA-16.2, "Stop Work"

7.5 QA-17.1, "Quality Assurance Records"

ATTACHMENT 2

PROPOSED REVISION TO EXISTING LICENSE CONDITIONS

The following revision is proposed to the conditions of Radioactive Material License No. R04100, Amendment 01. Existing license wording is shown, with proposed textual changes underlined (for text insertions) or struck through (for deletions).

LC 193.

193. Except as specifically provided otherwise by this license, the Licensee must possess and dispose of low-level radioactive waste authorized by the license in accordance with statements, representations, and procedures contained in the following:

Original application dated August 3, 2004, and subsequent revisions.

Application for administrative amendment to change the RSO, dated November 17, 2009.

Application for administrative amendment to update the Quality Assurance Plan and Quality Assurance Procedures, dated March 5, 2010.